Dokumentvorlage, Version vom 21.02.2019

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Abrocitinib (CIBINQO®)

PFIZER PHARMA GmbH
als örtlicher Vertreter des Zulassungsinhabers
Pfizer Europe MA EEIG

Modul 4 A

Behandlung von mittelschwerer bis schwerer atopischer Dermatitis bei Erwachsenen, die für eine systemische Therapie infrage kommen

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

Stand: 14.01.2022

Anhang 4-G: Zusatzanalysen

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(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	362	365
	Week 26	N	301	324
		Responders, n (%)	254 (84.4)	261 (80.6)
		95% CI	(80.3, 88.5)	(76.2, 84.9)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0486	
		95% CI	(0.9758, 1.1267)	
		Two-sided P-value	0.1961	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adea Table Generation: 06SEP2021 (05:22)
Output File: ./nda1_cdisc/B7451050_GBA/adea_mk3_1_2

Table 14.2.2.6.1.1.3 Abrocitinib
Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 - (FAS, Supplementary Analysis 2)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	362	365
	Week 26	N	348	361
		Number of Subjects with observed Case, N1 (%)	314 (90.2)	337 (93.4)
		Number of Subjects with NRI, N2 (%)	34 (9.8)	24 (6.6)
		Number of Subjects Missing Cases without NRI, N3 (%)	14 (3.9)	4 (1.1)
		Responders, n (%)	265 (76.1)	272 (75.3)
		95% CI	(71.7, 80.6)	(70.9, 79.8)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0106	
		95% CI	(0.9298, 1.0983)	
		Two-sided P-value	0.8047	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N of Week 26); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.2.6.1.1.4 Abrocitinib
Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 - (FAS, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	362	365
		Number of Subjects with Missing Response Imputed, N4 (%)	48 (13.3)	28 (7.7)
		Estimated Response Rate (%)	82.5	80.6
		95% CI	(78.3, 86.7)	(76.4, 84.7)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0248	
		95% CI	(0.9533, 1.1017)	
		Two-sided P-value	0.5068	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MI = multiple imputation; MAR = missing at random.

Table 14.2.2.6.2.1.2 Abrocitinib
Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 - (FAS, Supplementary Analysis 1)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	362	365
	Week 26	N	301	324
		Responders, n (%)	190 (63.1)	172 (53.1)
		95% CI	(57.7, 68.6)	(47.7, 58.5)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.1900	
		95% CI	(1.0410, 1.3603)	
		Two-sided P-value	0.0108	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.
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Output File: ./nda1_cdisc/B7451050_GBA/adea_mk3_2_2

Table 14.2.2.6.2.1.3 Abrocitinib
Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 - (FAS, Supplementary Analysis 2)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	362	365
	Week 26	N	348	361
		Number of Subjects with observed Case, N1 (%)	314 (90.2)	337 (93.4)
		Number of Subjects with NRI, N2 (%)	34 (9.8)	24 (6.6)
		Number of Subjects Missing Cases without NRI, N3 (%)	14 (3.9)	4 (1.1)
		Responders, n (%)	197 (56.6)	180 (49.9)
		95% CI	(51.4, 61.8)	(44.7, 55.0)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.1353	
		95% CI	(0.9885, 1.3039)	
		Two-sided P-value	0.0725	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N of Week 26); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.2.6.2.1.4 Abrocitinib
Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 - (FAS, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	362	365
		Number of Subjects with Missing Response Imputed, N4 (%)	48 (13.3)	28 (7.7)
		Estimated Response Rate (%)	61.6	53.2
		95% CI	(56.3, 66.9)	(47.9, 58.5)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.1586	
		95% CI	(1.0163, 1.3207)	
		Two-sided P-value	0.0277	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MI = multiple imputation; MAR = missing at random.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 4, Supplementary Analysis 1)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	357	364
	Week 26	N	311	327
		Responders, n (%)	241 (77.5)	229 (70.0)
		95% CI	(72.9, 82.1)	(65.1, 75.0)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.1055	
		95% CI	(1.0077, 1.2128)	
		Two-sided P-value	0.0338	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.
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Output File: ./nda1_cdisc/B7451050_GBA/adnr_mk3_1_2

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 4, Supplementary Analysis 2)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	357	364
	Week 26	N	354	363
		Number of Subjects with observed Case, N1 (%)	324 (91.5)	340 (93.7)
		Number of Subjects with NRI, N2 (%)	30 (8.5)	23 (6.3)
		Number of Subjects Missing Cases without NRI, N3 (%)	3 (0.8)	1 (0.3)
		Responders, n (%)	250 (70.6)	238 (65.6)
		95% CI	(65.9, 75.4)	(60.7, 70.5)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0769	
		95% CI	(0.9744, 1.1903)	
		Two-sided P-value	0.1466	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N of Week 26); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 - (FAS with Baseline >= 4, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	357	364
		Number of Subjects with Missing Response Imputed, N4 (%)	33 (9.2)	24 (6.6)
		Estimated Response Rate (%)	75.5	69.9
		95% CI	(70.9, 80.2)	(65.1, 74.7)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0800	
		95% CI	(0.9847, 1.1846)	
		Two-sided P-value	0.1026	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MI = multiple imputation; MAR = missing at random.

Table 14.2.6.5.2 Abrocitinib
Proportion of Subjects with DLQI < 2 Response at Week 26 (FAS with Baseline >= 2, Supplementary Analysis 1)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	358	361
	Week 26	N	300	321
		Responders, n (%)	137 (45.7)	114 (35.5)
		95% CI	(40.0, 51.3)	(30.3, 40.7)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.2875	
		95% CI	(1.0623, 1.5606)	
		Two-sided P-value	0.0100	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI =Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N).
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.6.5.3 Abrocitinib
Proportion of Subjects with DLQI < 2 Response at Week 26 (FAS with Baseline >= 2, Supplementary Analysis 2)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	358	361
	Week 26	N	346	358
		Number of Subjects with observed Case, N1 (%)	313 (90.5)	334 (93.3)
		Number of Subjects with NRI, N2 (%)	33 (9.5)	24 (6.7)
		Number of Subjects Missing Cases without NRI, N3 (%)	12 (3.4)	3 (0.8)
		Responders, n (%)	142 (41.0)	117 (32.7)
		95% CI	(35.9, 46.2)	(27.8, 37.5)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.2559	
		95% CI	(1.0333, 1.5265)	
		Two-sided P-value	0.0221	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI =Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (01:50) Source Data: adli_e Table Generation: 13SEP2021 (03:35)
Output File: ./nda1_cdisc/B7451050_GBA/adli_mk3_1_3

Table 14.2.6.5.4 Abrocitinib
Proportion of Subjects with DLQI < 2 Response at Week 26 (FAS with Baseline >= 2, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	358	361
		Number of Subjects with Missing Response Imputed, N4 (%)	45 (12.6)	27 (7.5)
		Estimated Response Rate (%)	44.2	35.2
		95% CI	(38.9, 49.6)	(30.1, 40.3)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.2568	
		95% CI	(1.0416, 1.5164)	
		Two-sided P-value	0.0171	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MAR = missing at random.

Table 14.2.6.10.2 Abrocitinib
Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 5, Supplementary Analysis 1)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	336	345
	Week 26	N	281	307
		Responders, n (%)	243 (86.5)	270 (87.9)
		95% CI	(82.5, 90.5)	(84.3, 91.6)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.9822	
		95% CI	(0.9233, 1.0448)	
		Two-sided P-value	0.5683	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI =Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N).
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.6.10.3 Abrocitinib
Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 5, Supplementary Analysis 2) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	336	345
	Week 26	N	324	342
		Number of Subjects with observed Case, N1 (%)	293 (90.4)	320 (93.6)
		Number of Subjects with NRI, N2 (%)	31 (9.6)	22 (6.4)
		Number of Subjects Missing Cases without NRI, N3 (%)	12 (3.6)	3 (0.9)
		Responders, n (%)	254 (78.4)	282 (82.5)
		95% CI	(73.9, 82.9)	(78.4, 86.5)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.9510	
		95% CI	(0.8825, 1.0247)	
		Two-sided P-value	0.1871	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI =Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.6.10.4 Abrocitinib
Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 5, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	336	345
		Number of Subjects with Missing Response Imputed, N4 (%)	43 (12.8)	25 (7.2)
		Estimated Response Rate (%)	85.4	87.8
		95% CI	(81.4, 89.4)	(84.2, 91.4)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.9726	
		95% CI	(0.9146, 1.0342)	
		Two-sided P-value	0.3748	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MAR = missing at random.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 15, Supplementary Analysis 1) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	357	361
	Week 26	N	299	321
		Responders, n (%)	13 (4.3)	6 (1.9)
		95% CI	(2.0, 6.7)	(0.4, 3.4)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	2.3647	
		95% CI	(0.9137, 6.1205)	
		Two-sided P-value	0.0761	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel;EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.;N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N).
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 15, Supplementary Analysis 2) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	357	361
	Week 26	N	345	358
		Number of Subjects with observed Case, N1 (%)	311 (90.1)	334 (93.3)
		Number of Subjects with NRI, N2 (%)	34 (9.9)	24 (6.7)
		Number of Subjects Missing Cases without NRI, N3 (%)	12 (3.4)	3 (0.8)
		Responders, n (%)	13 (3.8)	6 (1.7)
		95% CI	(1.8, 5.8)	(0.3, 3.0)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	2.2404	
		95% CI	(0.8655, 5.7996)	
		Two-sided P-value	0.0965	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 15, Supplementary Analysis 3) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	357	361
		Number of Subjects with Missing Response Imputed, N4 (%)	46 (12.9)	27 (7.5)
		Estimated Response Rate (%)	4.4	1.8
		95% CI	(2.1, 6.7)	(0.4, 3.2)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	2.4632	
		95% CI	(0.9602, 6.3187)	
		Two-sided P-value	0.0607	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MAR = missing at random.

Proportion of Subjects Achieving Depression of HADS >= 4 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 4, Supplementary Analysis 1)

(Protocol B7451050)

			Abrocitinib 200mg QD	**Dupilumab 300mg Q2W**
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	131	141
	Week 26	N	112	121
		Responders, n (%)	44 (39.3)	44 (36.4)
		95% CI	(30.2, 48.3)	(27.8, 44.9)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0849	
		95% CI	(0.7698, 1.5290)	
		Two-sided P-value	0.6414	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; HADS = hospital anxiety and depression scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N).
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.
PFIZER CONFIDENTIAL SDTM Creation: 10AUG2021 (02:11) Source Data: adhl Table Generation: 14SEP2021 (01:31)
Output File: ./nda1_cdisc/B7451050_GBA/adhl_mk3_2

Proportion of Subjects Achieving Depression of HADS >= 4 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 4, Supplementary Analysis 2)

(Protocol B7451050)

			Abrocitinib 200mg QD	**Dupilumab 300mg Q2W**
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	131	141
	Week 26	N	128	139
		Number of Subjects with observed Case, N1 (%)	117 (91.4)	128 (92.1)
		Number of Subjects with NRI, N2 (%)	11 (8.6)	11 (7.9)
		Number of Subjects Missing Cases without NRI, N3 (%)	3 (2.3)	2 (1.4)
		Responders, n (%)	46 (35.9)	47 (33.8)
		95% CI	(27.6, 44.2)	(25.9, 41.7)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0707	
		95% CI	(0.7616, 1.5052)	
		Two-sided P-value	0.6945	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; HADS = hospital anxiety and depression scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.
PFIZER CONFIDENTIAL SDTM Creation: 10AUG2021 (02:11) Source Data: adhl_e Table Generation: 14SEP2021 (01:31)
Output File: ./nda1_cdisc/B7451050_GBA/adhl_mk3_3

Proportion of Subjects Achieving Depression of HADS >= 4 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 4, Supplementary Analysis 3)

(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	131	141
		Number of Subjects with Missing Response Imputed, N4 (%)	14 (10.7)	13 (9.2)
		Estimated Response Rate (%)	37.7	36.2
		95% CI	(29.1, 46.2)	(28.1, 44.3)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0474	
		95% CI	(0.7527, 1.4574)	
		Two-sided P-value	0.7835	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; HADS = hospital anxiety and depression scale; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MAR = missing at random.

Proportion of Subjects Achieving Anxiety of HADS >= 4 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 4, Supplementary Analysis 1) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	222	237
	Week 26	N	182	204
		Responders, n (%)	55 (30.2)	63 (30.9)
		95% CI	(23.5, 36.9)	(24.5, 37.2)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.9673	
		95% CI	(0.7170, 1.3048)	
		Two-sided P-value	0.8276	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; HADS = hospital anxiety and depression scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N).
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects Achieving Anxiety of HADS >= 4 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 4, Supplementary Analysis 2) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	222	237
	Week 26	N	215	234
		Number of Subjects with observed Case, N1 (%)	191 (88.8)	215 (91.9)
		Number of Subjects with NRI, N2 (%)	24 (11.2)	19 (8.1)
		Number of Subjects Missing Cases without NRI, N3 (%)	7 (3.2)	3 (1.3)
		Responders, n (%)	58 (27.0)	67 (28.6)
		95% CI	(21.0, 32.9)	(22.8, 34.4)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.9278	
		95% CI	(0.6900, 1.2475)	
		Two-sided P-value	0.6197	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; HADS = hospital anxiety and depression scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects Achieving Anxiety of HADS >= 4 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 4, Supplementary Analysis 3) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	222	237
		Number of Subjects with Missing Response Imputed, N4 (%)	31 (14.0)	22 (9.3)
		Estimated Response Rate (%)	29.0	30.5
		95% CI	(22.8, 35.3)	(24.5, 36.5)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.9381	
		95% CI	(0.7022, 1.2532)	
		Two-sided P-value	0.6653	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; HADS = hospital anxiety and depression scale; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MAR = missing at random.

Proportion of Subjects Achieving Depression of HADS < 8 Points Response criteria at Week 26 (FAS with Baseline >= 8, Supplementary Analysis 1) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	39	38
	Week 26	N	32	36
		Responders, n (%)	17 (53.1)	26 (72.2)
		95% CI	(35.8, 70.4)	(57.6, 86.9)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.7418	
		95% CI	(0.5072, 1.0851)	
		Two-sided P-value	0.1238	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; HADS = hospital anxiety and depression scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N).
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects Achieving Depression of HADS < 8 Points Response criteria at Week 26 (FAS with Baseline >= 8, Supplementary Analysis 2) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	39	38
	Week 26	N	38	38
		Number of Subjects with observed Case, N1 (%)	35 (92.1)	38 (100.0)
		Number of Subjects with NRI, N2 (%)	3 (7.9)	0
		Number of Subjects Missing Cases without NRI, N3 (%)	1 (2.6)	0
		Responders, n (%)	19 (50.0)	26 (68.4)
		95% CI	(34.1, 65.9)	(53.6, 83.2)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.7319	
		95% CI	(0.4985, 1.0745)	
		Two-sided P-value	0.1111	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; HADS = hospital anxiety and depression scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects Achieving Depression of HADS < 8 Points Response criteria at Week 26 (FAS with Baseline >= 8, Supplementary Analysis 3) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	39	38
		Number of Subjects with Missing Response Imputed, N4 (%)	4 (10.3)	0
		Estimated Response Rate (%)	58.2	68.4
		95% CI	(42.5, 73.9)	(., .)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.8533	
		95% CI	(0.6045, 1.2047)	
		Two-sided P-value	0.3674	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; HADS = hospital anxiety and depression scale; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MAR = missing at random.

Table 14.2.9.15.2 Abrocitinib
Proportion of Subjects Achieving Anxiety of HADS < 8 Points Response criteria at Week 26 (FAS with Baseline >= 8, Supplementary Analysis 1) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	94	92
	Week 26	N	76	77
		Responders, n (%)	42 (55.3)	49 (63.6)
		95% CI	(44.1, 66.4)	(52.9, 74.4)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.8675	
		95% CI	(0.6668, 1.1287)	
		Two-sided P-value	0.2899	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; HADS = hospital anxiety and depression scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N).
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.
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Proportion of Subjects Achieving Anxiety of HADS < 8 Points Response criteria at Week 26 (FAS with Baseline >= 8, Supplementary Analysis 2) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	94	92
	Week 26	N	90	91
		Number of Subjects with observed Case, N1 (%)	81 (90.0)	83 (91.2)
		Number of Subjects with NRI, N2 (%)	9 (10.0)	8 (8.8)
		Number of Subjects Missing Cases without NRI, N3 (%)	4 (4.3)	1 (1.1)
		Responders, n (%)	44 (48.9)	54 (59.3)
		95% CI	(38.6, 59.2)	(49.2, 69.4)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.8310	
		95% CI	(0.6353, 1.0870)	
		Two-sided P-value	0.1766	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; HADS = hospital anxiety and depression scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.9.15.4 Abrocitinib
Proportion of Subjects Achieving Anxiety of HADS < 8 Points Response criteria at Week 26 (FAS with Baseline >= 8, Supplementary Analysis 3) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	94	92
		Number of Subjects with Missing Response Imputed, N4 (%)	13 (13.8)	9 (9.8)
		Estimated Response Rate (%)	56.3	64.9
		95% CI	(45.8, 66.8)	(54.8, 74.9)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.8693	
		95% CI	(0.6823, 1.1075)	
		Two-sided P-value	0.2570	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; HADS = hospital anxiety and depression scale; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MAR = missing at random.

Table 14.2.10.8.2 Abrocitinib
Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 (FAS with Baseline >= 3, Supplementary Analysis 1)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	358	363
	Week 26	N	299	320
		Responders, n (%)	106 (35.5)	69 (21.6)
		95% CI	(30.0, 40.9)	(17.1, 26.1)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.6452	
		95% CI	(1.2700, 2.1312)	
		Two-sided P-value	0.0002	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N).
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.10.8.3 Abrocitinib
Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 (FAS with Baseline >= 3, Supplementary Analysis 2)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	358	363
	Week 26	N	346	359
		Number of Subjects with observed Case, N1 (%)	312 (90.2)	332 (92.5)
		Number of Subjects with NRI, N2 (%)	34 (9.8)	27 (7.5)
		Number of Subjects Missing Cases without NRI, N3 (%)	12 (3.4)	4 (1.1)
		Responders, n (%)	110 (31.8)	71 (19.8)
		95% CI	(26.9, 36.7)	(15.7, 23.9)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.6075	
		95% CI	(1.2404, 2.0834)	
		Two-sided P-value	0.0003	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.10.8.4 Abrocitinib
Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 (FAS with Baseline >= 3, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	358	363
		Number of Subjects with Missing Response Imputed, N4 (%)	46 (12.8)	31 (8.5)
		Estimated Response Rate (%)	34.6	21.5
		95% CI	(29.4, 39.8)	(17.2, 25.9)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.6087	
		95% CI	(1.2497, 2.0708)	
		Two-sided P-value	0.0002	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MAR = missing at random.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 5, Supplementary Analysis 1)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	356	363
	Week 26	N	297	320
		Responders, n (%)	271 (91.2)	289 (90.3)
		95% CI	(88.0, 94.5)	(87.1, 93.6)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0094	
		95% CI	(0.9601, 1.0612)	
		Two-sided P-value	0.7147	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N).
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 5, Supplementary Analysis 2)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	356	363
	Week 26	N	344	359
		Number of Subjects with observed Case, N1 (%)	310 (90.1)	332 (92.5)
		Number of Subjects with NRI, N2 (%)	34 (9.9)	27 (7.5)
		Number of Subjects Missing Cases without NRI, N3 (%)	12 (3.4)	4 (1.1)
		Responders, n (%)	283 (82.3)	301 (83.8)
		95% CI	(78.2, 86.3)	(80.0, 87.7)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.9807	
		95% CI	(0.9176, 1.0482)	
		Two-sided P-value	0.5661	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 5, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	356	363
		Number of Subjects with Missing Response Imputed, N4 (%)	46 (12.9)	31 (8.5)
		Estimated Response Rate (%)	90.5	90.2
		95% CI	(87.2, 93.7)	(86.9, 93.4)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0026	
		95% CI	(0.9532, 1.0545)	
		Two-sided P-value	0.9203	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MAR = missing at random.

Table 14.2.11.7.2 Abrocitinib
Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 15, Supplementary Analysis 1)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	362	363
	Week 26	N	301	320
		Responders, n (%)	131 (43.5)	117 (36.6)
		95% CI	(37.9, 49.1)	(31.3, 41.8)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.1831	
		95% CI	(0.9774, 1.4323)	
		Two-sided P-value	0.0845	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N).
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:37) Source Data: adom Table Generation: 12SEP2021 (10:36)
Output File: ./nda1_cdisc/B7451050_GBA/adom_mk3_2

Table 14.2.11.7.3 Abrocitinib
Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 15, Supplementary Analysis 2)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	362	363
	Week 26	N	348	359
		Number of Subjects with observed Case, N1 (%)	314 (90.2)	332 (92.5)
		Number of Subjects with NRI, N2 (%)	34 (9.8)	27 (7.5)
		Number of Subjects Missing Cases without NRI, N3 (%)	14 (3.9)	4 (1.1)
		Responders, n (%)	139 (39.9)	122 (34.0)
		95% CI	(34.8, 45.1)	(29.1, 38.9)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.1748	
		95% CI	(0.9706, 1.4219)	
		Two-sided P-value	0.0982	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.11.7.4 Abrocitinib
Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 15, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	362	363
		Number of Subjects with Missing Response Imputed, N4 (%)	48 (13.3)	31 (8.5)
		Estimated Response Rate (%)	43.8	37.0
		95% CI	(38.4, 49.2)	(31.9, 42.2)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.1805	
		95% CI	(0.9829, 1.4179)	
		Two-sided P-value	0.0759	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MAR = missing at random.

Table 14.2.11.8.2 Abrocitinib
Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 15, Supplementary Analysis 1)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	362	364
	Week 26	N	301	321
		Responders, n (%)	139 (46.2)	140 (43.6)
		95% CI	(40.5, 51.8)	(38.2, 49.0)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0537	
		95% CI	(0.8866, 1.2524)	
		Two-sided P-value	0.5524	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N).
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:37) Source Data: adom Table Generation: 12SEP2021 (10:36)
Output File: ./nda1_cdisc/B7451050_GBA/adom_mk3_6

Table 14.2.11.8.3 Abrocitinib
Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 15, Supplementary Analysis 2)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	362	364
	Week 26	N	348	360
		Number of Subjects with observed Case, N1 (%)	314 (90.2)	333 (92.5)
		Number of Subjects with NRI, N2 (%)	34 (9.8)	27 (7.5)
		Number of Subjects Missing Cases without NRI, N3 (%)	14 (3.9)	4 (1.1)
		Responders, n (%)	147 (42.2)	146 (40.6)
		95% CI	(37.1, 47.4)	(35.5, 45.6)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0408	
		95% CI	(0.8749, 1.2380)	
		Two-sided P-value	0.6518	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.11.8.4 Abrocitinib
Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 15, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	362	364
		Number of Subjects with Missing Response Imputed, N4 (%)	48 (13.3)	31 (8.5)
		Estimated Response Rate (%)	47.1	44.1
		95% CI	(41.6, 52.5)	(38.9, 49.4)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0651	
		95% CI	(0.9037, 1.2553)	
		Two-sided P-value	0.4520	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MAR = missing at random.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 4, Supplementary Analysis 1) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	316	325
	Week 26	N	263	284
		Responders, n (%)	205 (77.9)	202 (71.1)
		95% CI	(72.9, 83.0)	(65.9, 76.4)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0960	
		95% CI	(0.9936, 1.2089)	
		Two-sided P-value	0.0671	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; NRS = Pruritus Numeric Rating Scale; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 4, Supplementary Analysis 2) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	316	325
	Week 26	N	303	322
		Number of Subjects with observed Case, N1 (%)	275 (90.8)	296 (91.9)
		Number of Subjects with NRI, N2 (%)	28 (9.2)	26 (8.1)
		Number of Subjects Missing Cases without NRI, N3 (%)	13 (4.1)	3 (0.9)
		Responders, n (%)	212 (70.0)	211 (65.5)
		95% CI	(64.8, 75.1)	(60.3, 70.7)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0679	
		95% CI	(0.9583, 1.1900)	
		Two-sided P-value	0.2345	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; NRS = Pruritus Numeric Rating Scale; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N of Week 26); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 4, Supplementary Analysis 3) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	316	325
		Number of Subjects with Missing Response Imputed, N4 (%)	41 (13.0)	29 (8.9)
		Estimated Response Rate (%)	75.4	71.0
		95% CI	(70.4, 80.4)	(65.9, 76.1)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0620	
		95% CI	(0.9627, 1.1715)	
		Two-sided P-value	0.2298	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MI = multiple imputation; MAR = missing at random.

Table 14.2.13.9.1.1.2 Abrocitinib
Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 - (FAS, Supplementary Analysis 1)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	362	365
	Week 26	N	300	323
		Responders, n (%)	152 (50.7)	133 (41.2)
		95% CI	(45.0, 56.3)	(35.8, 46.5)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.2287	
		95% CI	(1.0349, 1.4587)	
		Two-sided P-value	0.0187	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; SCORAD = scoring atopic dermatitis; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.13.9.1.1.3 Abrocitinib
Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 - (FAS, Supplementary Analysis 2)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	362	365
	Week 26	N	347	359
		Number of Subjects with observed Case, N1 (%)	313 (90.2)	335 (93.3)
		Number of Subjects with NRI, N2 (%)	34 (9.8)	24 (6.7)
		Number of Subjects Missing Cases without NRI, N3 (%)	15 (4.1)	6 (1.6)
		Responders, n (%)	157 (45.2)	136 (37.9)
		95% CI	(40.0, 50.5)	(32.9, 42.9)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.1944	
		95% CI	(1.0017, 1.4243)	
		Two-sided P-value	0.0478	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; SCORAD = scoring atopic dermatitis; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N of Week 26); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.13.9.1.1.4 Abrocitinib
Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 - (FAS, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	362	365
		Number of Subjects with Missing Response Imputed, N4 (%)	49 (13.5)	30 (8.2)
		Estimated Response Rate (%)	48.8	40.2
		95% CI	(43.3, 54.2)	(35.0, 45.4)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.2113	
		95% CI	(1.0213, 1.4365)	
		Two-sided P-value	0.0276	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MI = multiple imputation; MAR = missing at random.

Table 14.2.13.9.2.1.2 Abrocitinib
Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 - (FAS, Supplementary Analysis 1)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	362	365
	Week 26	N	300	323
		Responders, n (%)	80 (26.7)	52 (16.1)
		95% CI	(21.7, 31.7)	(12.1, 20.1)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.6570	
		95% CI	(1.2134, 2.2628)	
		Two-sided P-value	0.0015	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; SCORAD = scoring atopic dermatitis; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.13.9.2.1.3 Abrocitinib
Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 - (FAS, Supplementary Analysis 2)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	362	365
	Week 26	N	347	359
		Number of Subjects with observed Case, N1 (%)	313 (90.2)	335 (93.3)
		Number of Subjects with NRI, N2 (%)	34 (9.8)	24 (6.7)
		Number of Subjects Missing Cases without NRI, N3 (%)	15 (4.1)	6 (1.6)
		Responders, n (%)	83 (23.9)	52 (14.5)
		95% CI	(19.4, 28.4)	(10.8, 18.1)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.6514	
		95% CI	(1.2066, 2.2600)	
		Two-sided P-value	0.0017	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; SCORAD = scoring atopic dermatitis; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N of Week 26); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.13.9.2.1.4 Abrocitinib
Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 - (FAS, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	362	365
		Number of Subjects with Missing Response Imputed, N4 (%)	49 (13.5)	30 (8.2)
		Estimated Response Rate (%)	25.6	15.6
		95% CI	(20.8, 30.3)	(11.7, 19.5)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.6385	
		95% CI	(1.2027, 2.2322)	
		Two-sided P-value	0.0017	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MI = multiple imputation; MAR = missing at random.

Table 14.2.13.9.3.1.2 Abrocitinib
Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 - (FAS with Baseline >= 2, Supplementary Analysis 1)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	329	333
	Week 26	N	273	295
		Responders, n (%)	253 (92.7)	265 (89.8)
		95% CI	(89.6, 95.8)	(86.4, 93.3)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0310	
		95% CI	(0.9802, 1.0845)	
		Two-sided P-value	0.2361	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; SCORAD = scoring atopic dermatitis; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.13.9.3.1.3 Abrocitinib
Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 - (FAS with Baseline >= 2, Supplementary Analysis 2)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	329	333
	Week 26	N	314	328
		Number of Subjects with observed Case, N1 (%)	285 (90.8)	307 (93.6)
		Number of Subjects with NRI, N2 (%)	29 (9.2)	21 (6.4)
		Number of Subjects Missing Cases without NRI, N3 (%)	15 (4.6)	5 (1.5)
		Responders, n (%)	262 (83.4)	276 (84.1)
		95% CI	(79.3, 87.6)	(80.2, 88.1)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.9917	
		95% CI	(0.9269, 1.0610)	
		Two-sided P-value	0.8079	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; SCORAD = scoring atopic dermatitis; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N of week 26); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.13.9.3.1.4 Abrocitinib
Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 - (FAS with Baseline >= 2, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	329	333
		Number of Subjects with Missing Response Imputed, N4 (%)	44 (13.4)	26 (7.8)
		Estimated Response Rate (%)	90.8	89.5
		95% CI	(87.3, 94.2)	(86.1, 92.9)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0140	
		95% CI	(0.9612, 1.0697)	
		Two-sided P-value	0.6098	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MI = multiple imputation; MAR = missing at random.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 - (FAS with Baseline >= 2, Supplementary Analysis 1)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 1: Observed Data	Baseline	N	362	365
	Week 26	N	300	323
		Responders, n (%)	273 (91.0)	294 (91.0)
		95% CI	(87.8, 94.2)	(87.9, 94.1)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.9990	
		95% CI	(0.9509, 1.0495)	
		Two-sided P-value	0.9674	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; SCORAD = scoring atopic dermatitis; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 - (FAS with Baseline >= 2, Supplementary Analysis 2)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 2: NRI after withdrawal	Baseline	N	362	365
	Week 26	N	347	359
		Number of Subjects with observed Case, N1 (%)	313 (90.2)	335 (93.3)
		Number of Subjects with NRI, N2 (%)	34 (9.8)	24 (6.7)
		Number of Subjects Missing Cases without NRI, N3 (%)	15 (4.1)	6 (1.6)
		Responders, n (%)	284 (81.8)	305 (85.0)
		95% CI	(77.8, 85.9)	(81.3, 88.7)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.9634	
		95% CI	(0.9022, 1.0287)	
		Two-sided P-value	0.2654	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; SCORAD = scoring atopic dermatitis; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
The denominators of N1 (%) and N2 (%) were N of Week 26. The denominator of N3 (%) was N of baseline.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 - (FAS with Baseline >= 2, Supplementary Analysis 3)
(Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Supplementary Analysis 3: Multiple Imputations	Week 26	N	362	365
		Number of Subjects with Missing Response Imputed, N4 (%)	49 (13.5)	30 (8.2)
		Estimated Response Rate (%)	89.9	90.5
		95% CI	(86.5, 93.2)	(87.3, 93.6)
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	0.9933	
		95% CI	(0.9442, 1.0451)	
		Two-sided P-value	0.7965	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
A logit-normal GLMM was fit with treatment, visit, treatment by visit interaction as fixed effects and a latent subject-level, zero mean, normally distributed random effect, with a logit link function. All observed data (ie, regardless of rescue therapy and without defining missing data as 'non-response') was used. Posterior distributions of the model parameters were estimated under a Bayesian framework. Under MAR, missing values were imputed 500 times by random Bernoulli draws using a posterior probability of response. For each such completed dataset, the estimates of the proportions and relative risk by CMH method between abrocitinib and dupilumab were obtained and Rubin's rule was used to combine the multiple estimates and standard errors across the imputed datasets and provide p-values.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; GLMM = generalized linear mixed model; N = number of subjects included in the analysis model; MI = multiple imputation; MAR = missing at random.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	230	247
	Week 26, N	230	247
	Number of Subjects with observed Case, N1 (%)	185 (80.4)	220 (89.1)
	Number of Subjects with NRI, N2 (%)	45 (19.6)	27 (10.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	154 (67.0)	179 (72.5)
	95% CI	(60.9, 73.0)	(66.9, 78.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9239	
	95% CI	(0.8203, 1.0406)	
	Two-sided P-value	0.1923	
Age (years) group: >=40	Baseline, N	132	118
	Week 26, N	132	118
	Number of Subjects with observed Case, N1 (%)	116 (87.9)	104 (88.1)
	Number of Subjects with NRI, N2 (%)	16 (12.1)	14 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	100 (75.8)	82 (69.5)
	95% CI	(68.4, 83.1)	(61.2, 77.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0902	
	95% CI	(0.9349, 1.2712)	
	Two-sided P-value	0.2707	
	P-value of interaction	0.0951	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	341	354
	Week 26, N	341	354
	Number of Subjects with observed Case, N1 (%)	284 (83.3)	314 (88.7)
	Number of Subjects with NRI, N2 (%)	57 (16.7)	40 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	239 (70.1)	255 (72.0)
	95% CI	(65.2, 74.9)	(67.4, 76.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9730	
	95% CI	(0.8848, 1.0699)	
	Two-sided P-value	0.5720	
Age (years) group: >=65	Baseline, N	21	11
	Week 26, N	21	11
	Number of Subjects with observed Case, N1 (%)	17 (81.0)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	4 (19.0)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Responders, n (%)	15 (71.4)	6 (54.5)
	95% CI	(52.1, 90.8)	(25.1, 84.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3095	
	95% CI	(0.7162, 2.3944)	
	Two-sided P-value	0.3811	
	P-value of interaction	0.3406	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Table 14.2.2.6.1.2 Abrocitinib
Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	193	204
	Week 26, N	193	204
	Number of Subjects with observed Case, N1 (%)	169 (87.6)	180 (88.2)
	Number of Subjects with NRI, N2 (%)	24 (12.4)	24 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	137 (71.0)	134 (65.7)
	95% CI	(64.6, 77.4)	(59.2, 72.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0807	
	95% CI	(0.9451, 1.2357)	
	Two-sided P-value	0.2568	
Sex: Female	Baseline, N	169	161
	Week 26, N	169	161
	Number of Subjects with observed Case, N1 (%)	132 (78.1)	144 (89.4)
	Number of Subjects with NRI, N2 (%)	37 (21.9)	17 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Table 14.2.2.6.1.2 Abrocitinib
Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	117 (69.2)	127 (78.9)
	95% CI	(62.3, 76.2)	(72.6, 85.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8776	
	95% CI	(0.7719, 0.9979)	
	Two-sided P-value	0.0464	
	P-value of interaction	0.0280	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	269	248
	Week 26, N	269	248
	Number of Subjects with observed Case, N1 (%)	221 (82.2)	220 (88.7)
	Number of Subjects with NRI, N2 (%)	48 (17.8)	28 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	192 (71.4)	180 (72.6)
	95% CI	(66.0, 76.8)	(67.0, 78.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9834	
	95% CI	(0.8831, 1.0951)	
	Two-sided P-value	0.7604	
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	25	26
	Week 26, N	25	26
	Number of Subjects with observed Case, N1 (%)	18 (72.0)	21 (80.8)
	Number of Subjects with NRI, N2 (%)	7 (28.0)	5 (19.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Responders, n (%)	12 (48.0)	16 (61.5)
	95% CI	(28.4, 67.6)	(42.8, 80.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.7800	
	95% CI	(0.4690, 1.2973)	
	Two-sided P-value	0.3384	
Race: ASIAN	Baseline, N	62	83
	Week 26, N	62	83
	Number of Subjects with observed Case, N1 (%)	56 (90.3)	75 (90.4)
	Number of Subjects with NRI, N2 (%)	6 (9.7)	8 (9.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	46 (74.2)	60 (72.3)
	95% CI	(63.3, 85.1)	(62.7, 81.9)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Table 14.2.2.6.1.2 Abrocitinib
Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0263	
	95% CI	(0.8418, 1.2514)	
	Two-sided P-value	0.7971	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	4 (66.7)	5 (62.5)
	95% CI	(28.9, 100.0)	(29.0, 96.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0667	
	95% CI	(0.4890, 2.3267)	
	Two-sided P-value	0.8712	
	P-value of interaction	0.7979	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	195
	Week 26, N	177	195
	Number of Subjects with observed Case, N1 (%)	142 (80.2)	169 (86.7)
	Number of Subjects with NRI, N2 (%)	35 (19.8)	26 (13.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	118 (66.7)	136 (69.7)
	95% CI	(59.7, 73.6)	(63.3, 76.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9559	
	95% CI	(0.8316, 1.0987)	
	Two-sided P-value	0.5255	
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	130 (86.7)	122 (92.4)
	Number of Subjects with NRI, N2 (%)	20 (13.3)	10 (7.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	111 (74.0)	94 (71.2)
	95% CI	(67.0, 81.0)	(63.5, 78.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0391	
	95% CI	(0.8997, 1.2002)	
	Two-sided P-value	0.6014	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	15 (88.2)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	2 (11.8)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	11 (64.7)	16 (84.2)
	95% CI	(42.0, 87.4)	(67.8, 100.0)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.7684	
	95% CI	(0.5143, 1.1480)	
	Two-sided P-value	0.1983	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	14 (77.8)	15 (78.9)
	95% CI	(58.6, 97.0)	(60.6, 97.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9852	
	95% CI	(0.7020, 1.3827)	
	Two-sided P-value	0.9312	
	P-value of interaction	0.5379	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	216	220
	Week 26, N	216	220
	Number of Subjects with observed Case, N1 (%)	178 (82.4)	195 (88.6)
	Number of Subjects with NRI, N2 (%)	38 (17.6)	25 (11.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	159 (73.6)	160 (72.7)
	95% CI	(67.7, 79.5)	(66.8, 78.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0122	
	95% CI	(0.9034, 1.1340)	
	Two-sided P-value	0.8350	
Baseline disease severity: Severe	Baseline, N	146	145
	Week 26, N	146	145
	Number of Subjects with observed Case, N1 (%)	123 (84.2)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	23 (15.8)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	95 (65.1)	101 (69.7)
	95% CI	(57.3, 72.8)	(62.2, 77.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9342	
	95% CI	(0.7959, 1.0965)	
	Two-sided P-value	0.4047	
	P-value of interaction	0.4236	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	40	51
	Week 26, N	40	51
	Number of Subjects with observed Case, N1 (%)	32 (80.0)	44 (86.3)
	Number of Subjects with NRI, N2 (%)	8 (20.0)	7 (13.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	26 (65.0)	34 (66.7)
	95% CI	(50.2, 79.8)	(53.7, 79.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9750	
	95% CI	(0.7231, 1.3147)	
	Two-sided P-value	0.8682	
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	322	314
	Week 26, N	322	314
	Number of Subjects with observed Case, N1 (%)	269 (83.5)	280 (89.2)
	Number of Subjects with NRI, N2 (%)	53 (16.5)	34 (10.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Responders, n (%)	228 (70.8)	227 (72.3)
	95% CI	(65.8, 75.8)	(67.3, 77.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9795	
	95% CI	(0.8880, 1.0803)	
	Two-sided P-value	0.6780	
	P-value of interaction	0.9774	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	132	136
	Week 26, N	132	136
	Number of Subjects with observed Case, N1 (%)	106 (80.3)	122 (89.7)
	Number of Subjects with NRI, N2 (%)	26 (19.7)	14 (10.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	92 (69.7)	108 (79.4)
	95% CI	(61.9, 77.5)	(72.6, 86.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8777	
	95% CI	(0.7620, 1.0109)	
	Two-sided P-value	0.0704	
Weight (kg): >=70 and <=100	Baseline, N	196	184
	Week 26, N	196	184
	Number of Subjects with observed Case, N1 (%)	168 (85.7)	166 (90.2)
	Number of Subjects with NRI, N2 (%)	28 (14.3)	18 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Responders, n (%)	142 (72.4)	129 (70.1)
	95% CI	(66.2, 78.7)	(63.5, 76.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0334	
	95% CI	(0.9093, 1.1744)	
	Two-sided P-value	0.6148	
Weight (kg): >100	Baseline, N	34	45
	Week 26, N	34	45
	Number of Subjects with observed Case, N1 (%)	27 (79.4)	36 (80.0)
	Number of Subjects with NRI, N2 (%)	7 (20.6)	9 (20.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	20 (58.8)	24 (53.3)
	95% CI	(42.3, 75.4)	(38.8, 67.9)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1029	
	95% CI	(0.7451, 1.6325)	
	Two-sided P-value	0.6243	
	P-value of interaction	0.1945	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	222	220
	Week 26, N	222	220
	Number of Subjects with observed Case, N1 (%)	183 (82.4)	195 (88.6)
	Number of Subjects with NRI, N2 (%)	39 (17.6)	25 (11.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	158 (71.2)	157 (71.4)
	95% CI	(65.2, 77.1)	(65.4, 77.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9973	
	95% CI	(0.8860, 1.1226)	
	Two-sided P-value	0.9643	
AD Duration (years) group: >=26	Baseline, N	140	145
	Week 26, N	140	145
	Number of Subjects with observed Case, N1 (%)	118 (84.3)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	22 (15.7)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Responders, n (%)	96 (68.6)	104 (71.7)
	95% CI	(60.9, 76.3)	(64.4, 79.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9560	
	95% CI	(0.8215, 1.1127)	
	Two-sided P-value	0.5615	
	P-value of interaction	0.6670	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	181	183
	Week 26, N	181	183
	Number of Subjects with observed Case, N1 (%)	145 (80.1)	161 (88.0)
	Number of Subjects with NRI, N2 (%)	36 (19.9)	22 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	124 (68.5)	129 (70.5)
	95% CI	(61.7, 75.3)	(63.9, 77.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9719	
	95% CI	(0.8481, 1.1136)	
	Two-sided P-value	0.6812	
Baseline EASI group: >25	Baseline, N	172	174
	Week 26, N	172	174
	Number of Subjects with observed Case, N1 (%)	148 (86.0)	156 (89.7)
	Number of Subjects with NRI, N2 (%)	24 (14.0)	18 (10.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Responders, n (%)	123 (71.5)	125 (71.8)
	95% CI	(64.8, 78.3)	(65.2, 78.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9954	
	95% CI	(0.8719, 1.1365)	
	Two-sided P-value	0.9461	
	P-value of interaction	0.8047	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	122	133
	Week 26, N	122	133
	Number of Subjects with observed Case, N1 (%)	100 (82.0)	120 (90.2)
	Number of Subjects with NRI, N2 (%)	22 (18.0)	13 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	87 (71.3)	95 (71.4)
	95% CI	(63.3, 79.3)	(63.8, 79.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9984	
	95% CI	(0.8545, 1.1665)	
	Two-sided P-value	0.9835	
Baseline % BSA group: >30-50	Baseline, N	132	121
	Week 26, N	132	121
	Number of Subjects with observed Case, N1 (%)	110 (83.3)	107 (88.4)
	Number of Subjects with NRI, N2 (%)	22 (16.7)	14 (11.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Responders, n (%)	95 (72.0)	86 (71.1)
	95% CI	(64.3, 79.6)	(63.0, 79.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0126	
	95% CI	(0.8666, 1.1832)	
	Two-sided P-value	0.8748	
Baseline % BSA group: >50	Baseline, N	108	111
	Week 26, N	108	111
	Number of Subjects with observed Case, N1 (%)	91 (84.3)	97 (87.4)
	Number of Subjects with NRI, N2 (%)	17 (15.7)	14 (12.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	72 (66.7)	80 (72.1)
	95% CI	(57.8, 75.6)	(63.7, 80.4)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9250	
	95% CI	(0.7752, 1.1037)	
	Two-sided P-value	0.3870	
	P-value of interaction	0.7288	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	172	176
	Week 26, N	172	176
	Number of Subjects with observed Case, N1 (%)	141 (82.0)	160 (90.9)
	Number of Subjects with NRI, N2 (%)	31 (18.0)	16 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	123 (71.5)	131 (74.4)
	95% CI	(64.8, 78.3)	(68.0, 80.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9608	
	95% CI	(0.8453, 1.0920)	
	Two-sided P-value	0.5401	
Prior AD medications: Topical Agents Only	Baseline, N	188	189
	Week 26, N	188	189
	Number of Subjects with observed Case, N1 (%)	158 (84.0)	164 (86.8)
	Number of Subjects with NRI, N2 (%)	30 (16.0)	25 (13.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Responders, n (%)	129 (68.6)	130 (68.8)
	95% CI	(62.0, 75.3)	(62.2, 75.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9976	
	95% CI	(0.8705, 1.1432)	
	Two-sided P-value	0.9723	
	P-value of interaction	0.6934	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	83	105
	Week 26, N	83	105
	Number of Subjects with observed Case, N1 (%)	74 (89.2)	95 (90.5)
	Number of Subjects with NRI, N2 (%)	9 (10.8)	10 (9.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	66 (79.5)	82 (78.1)
	95% CI	(70.8, 88.2)	(70.2, 86.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0182	
	95% CI	(0.8773, 1.1817)	
	Two-sided P-value	0.8122	
Baseline PP-NRS group: >=7	Baseline, N	274	259
	Week 26, N	274	259
	Number of Subjects with observed Case, N1 (%)	225 (82.1)	228 (88.0)
	Number of Subjects with NRI, N2 (%)	49 (17.9)	31 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Responders, n (%)	186 (67.9)	179 (69.1)
	95% CI	(62.4, 73.4)	(63.5, 74.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9822	
	95% CI	(0.8754, 1.1021)	
	Two-sided P-value	0.7601	
	P-value of interaction	0.7079	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	230	247
	Week 26, N	230	247
	Number of Subjects with observed Case, N1 (%)	185 (80.4)	220 (89.1)
	Number of Subjects with NRI, N2 (%)	45 (19.6)	27 (10.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	114 (49.6)	113 (45.7)
	95% CI	(43.1, 56.0)	(39.5, 52.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0834	
	95% CI	(0.8975, 1.3078)	
	Two-sided P-value	0.4042	
Age (years) group: >=40	Baseline, N	132	118
	Week 26, N	132	118
	Number of Subjects with observed Case, N1 (%)	116 (87.9)	104 (88.1)
	Number of Subjects with NRI, N2 (%)	16 (12.1)	14 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	76 (57.6)	59 (50.0)
	95% CI	(49.1, 66.0)	(41.0, 59.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1515	
	95% CI	(0.9127, 1.4527)	
	Two-sided P-value	0.2341	
	P-value of interaction	0.6895	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	341	354
	Week 26, N	341	354
	Number of Subjects with observed Case, N1 (%)	284 (83.3)	314 (88.7)
	Number of Subjects with NRI, N2 (%)	57 (16.7)	40 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	178 (52.2)	167 (47.2)
	95% CI	(46.9, 57.5)	(42.0, 52.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1065	
	95% CI	(0.9525, 1.2854)	
	Two-sided P-value	0.1857	
Age (years) group: >=65	Baseline, N	21	11
	Week 26, N	21	11
	Number of Subjects with observed Case, N1 (%)	17 (81.0)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	4 (19.0)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Responders, n (%)	12 (57.1)	5 (45.5)
	95% CI	(36.0, 78.3)	(16.0, 74.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2571	
	95% CI	(0.5963, 2.6503)	
	Two-sided P-value	0.5476	
	P-value of interaction	0.7423	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	193	204
	Week 26, N	193	204
	Number of Subjects with observed Case, N1 (%)	169 (87.6)	180 (88.2)
	Number of Subjects with NRI, N2 (%)	24 (12.4)	24 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	95 (49.2)	83 (40.7)
	95% CI	(42.2, 56.3)	(33.9, 47.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2098	
	95% CI	(0.9718, 1.5061)	
	Two-sided P-value	0.0883	
Sex: Female	Baseline, N	169	161
	Week 26, N	169	161
	Number of Subjects with observed Case, N1 (%)	132 (78.1)	144 (89.4)
	Number of Subjects with NRI, N2 (%)	37 (21.9)	17 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Table 14.2.2.6.2.2 Abrocitinib
Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	95 (56.2)	89 (55.3)
	95% CI	(48.7, 63.7)	(47.6, 63.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0169	
	95% CI	(0.8389, 1.2326)	
	Two-sided P-value	0.8645	
	P-value of interaction	0.2428	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	269	248
	Week 26, N	269	248
	Number of Subjects with observed Case, N1 (%)	221 (82.2)	220 (88.7)
	Number of Subjects with NRI, N2 (%)	48 (17.8)	28 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	143 (53.2)	122 (49.2)
	95% CI	(47.2, 59.1)	(43.0, 55.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0806	
	95% CI	(0.9125, 1.2797)	
	Two-sided P-value	0.3687	
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	25	26
	Week 26, N	25	26
	Number of Subjects with observed Case, N1 (%)	18 (72.0)	21 (80.8)
	Number of Subjects with NRI, N2 (%)	7 (28.0)	5 (19.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Responders, n (%)	11 (44.0)	7 (26.9)
	95% CI	(24.5, 63.5)	(9.9, 44.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6343	
	95% CI	(0.7549, 3.5381)	
	Two-sided P-value	0.2126	
Race: ASIAN	Baseline, N	62	83
	Week 26, N	62	83
	Number of Subjects with observed Case, N1 (%)	56 (90.3)	75 (90.4)
	Number of Subjects with NRI, N2 (%)	6 (9.7)	8 (9.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	32 (51.6)	40 (48.2)
	95% CI	(39.2, 64.1)	(37.4, 58.9)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0710	
	95% CI	(0.7712, 1.4873)	
	Two-sided P-value	0.6824	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	4 (66.7)	3 (37.5)
	95% CI	(28.9, 100.0)	(4.0, 71.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.7778	
	95% CI	(0.6168, 5.1236)	
	Two-sided P-value	0.2867	
	P-value of interaction	0.6013	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	195
	Week 26, N	177	195
	Number of Subjects with observed Case, N1 (%)	142 (80.2)	169 (86.7)
	Number of Subjects with NRI, N2 (%)	35 (19.8)	26 (13.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	88 (49.7)	89 (45.6)
	95% CI	(42.4, 57.1)	(38.6, 52.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0893	
	95% CI	(0.8802, 1.3480)	
	Two-sided P-value	0.4314	
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	130 (86.7)	122 (92.4)
	Number of Subjects with NRI, N2 (%)	20 (13.3)	10 (7.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	83 (55.3)	60 (45.5)
	95% CI	(47.4, 63.3)	(37.0, 53.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2173	
	95% CI	(0.9616, 1.5410)	
	Two-sided P-value	0.1021	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	15 (88.2)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	2 (11.8)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (35.3)	10 (52.6)
	95% CI	(12.6, 58.0)	(30.2, 75.1)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.6706	
	95% CI	(0.3098, 1.4515)	
	Two-sided P-value	0.3104	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	13 (72.2)	13 (68.4)
	95% CI	(51.5, 92.9)	(47.5, 89.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0556	
	95% CI	(0.6944, 1.6046)	
	Two-sided P-value	0.8002	
	P-value of interaction	0.5107	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	216	220
	Week 26, N	216	220
	Number of Subjects with observed Case, N1 (%)	178 (82.4)	195 (88.6)
	Number of Subjects with NRI, N2 (%)	38 (17.6)	25 (11.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	119 (55.1)	104 (47.3)
	95% CI	(48.5, 61.7)	(40.7, 53.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1654	
	95% CI	(0.9692, 1.4013)	
	Two-sided P-value	0.1036	
Baseline disease severity: Severe	Baseline, N	146	145
	Week 26, N	146	145
	Number of Subjects with observed Case, N1 (%)	123 (84.2)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	23 (15.8)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI) (Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	71 (48.6)	68 (46.9)
	95% CI	(40.5, 56.7)	(38.8, 55.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0370	
	95% CI	(0.8154, 1.3188)	
	Two-sided P-value	0.7673	
	P-value of interaction	0.4499	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	40	51
	Week 26, N	40	51
	Number of Subjects with observed Case, N1 (%)	32 (80.0)	44 (86.3)
	Number of Subjects with NRI, N2 (%)	8 (20.0)	7 (13.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	18 (45.0)	24 (47.1)
	95% CI	(29.6, 60.4)	(33.4, 60.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9563	
	95% CI	(0.6100, 1.4991)	
	Two-sided P-value	0.8454	
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	322	314
	Week 26, N	322	314
	Number of Subjects with observed Case, N1 (%)	269 (83.5)	280 (89.2)
	Number of Subjects with NRI, N2 (%)	53 (16.5)	34 (10.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Responders, n (%)	172 (53.4)	148 (47.1)
	95% CI	(48.0, 58.9)	(41.6, 52.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1333	
	95% CI	(0.9702, 1.3237)	
	Two-sided P-value	0.1144	
	P-value of interaction	0.4840	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	132	136
	Week 26, N	132	136
	Number of Subjects with observed Case, N1 (%)	106 (80.3)	122 (89.7)
	Number of Subjects with NRI, N2 (%)	26 (19.7)	14 (10.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	75 (56.8)	70 (51.5)
	95% CI	(48.4, 65.3)	(43.1, 59.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1039	
	95% CI	(0.8852, 1.3766)	
	Two-sided P-value	0.3802	
Weight (kg): >=70 and <=100	Baseline, N	196	184
	Week 26, N	196	184
	Number of Subjects with observed Case, N1 (%)	168 (85.7)	166 (90.2)
	Number of Subjects with NRI, N2 (%)	28 (14.3)	18 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Responders, n (%)	102 (52.0)	85 (46.2)
	95% CI	(45.0, 59.0)	(39.0, 53.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1265	
	95% CI	(0.9169, 1.3840)	
	Two-sided P-value	0.2567	
Weight (kg): >100	Baseline, N	34	45
	Week 26, N	34	45
	Number of Subjects with observed Case, N1 (%)	27 (79.4)	36 (80.0)
	Number of Subjects with NRI, N2 (%)	7 (20.6)	9 (20.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	13 (38.2)	17 (37.8)
	95% CI	(21.9, 54.6)	(23.6, 51.9)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0121	
	95% CI	(0.5733, 1.7869)	
	Two-sided P-value	0.9669	
	P-value of interaction	0.9402	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Table 14.2.2.6.2.2 Abrocitinib
Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	222	220
	Week 26, N	222	220
	Number of Subjects with observed Case, N1 (%)	183 (82.4)	195 (88.6)
	Number of Subjects with NRI, N2 (%)	39 (17.6)	25 (11.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	120 (54.1)	105 (47.7)
	95% CI	(47.5, 60.6)	(41.1, 54.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1326	
	95% CI	(0.9423, 1.3613)	
	Two-sided P-value	0.1847	
AD Duration (years) group: >=26	Baseline, N	140	145
	Week 26, N	140	145
	Number of Subjects with observed Case, N1 (%)	118 (84.3)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	22 (15.7)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Responders, n (%)	70 (50.0)	67 (46.2)
	95% CI	(41.7, 58.3)	(38.1, 54.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0821	
	95% CI	(0.8500, 1.3776)	
	Two-sided P-value	0.5218	
	P-value of interaction	0.7685	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	181	183
	Week 26, N	181	183
	Number of Subjects with observed Case, N1 (%)	145 (80.1)	161 (88.0)
	Number of Subjects with NRI, N2 (%)	36 (19.9)	22 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	98 (54.1)	88 (48.1)
	95% CI	(46.9, 61.4)	(40.8, 55.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1259	
	95% CI	(0.9204, 1.3774)	
	Two-sided P-value	0.2488	
Baseline EASI group: >25	Baseline, N	172	174
	Week 26, N	172	174
	Number of Subjects with observed Case, N1 (%)	148 (86.0)	156 (89.7)
	Number of Subjects with NRI, N2 (%)	24 (14.0)	18 (10.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Responders, n (%)	88 (51.2)	78 (44.8)
	95% CI	(43.7, 58.6)	(37.4, 52.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1413	
	95% CI	(0.9157, 1.4225)	
	Two-sided P-value	0.2394	
	P-value of interaction	0.9290	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	122	133
	Week 26, N	122	133
	Number of Subjects with observed Case, N1 (%)	100 (82.0)	120 (90.2)
	Number of Subjects with NRI, N2 (%)	22 (18.0)	13 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	68 (55.7)	70 (52.6)
	95% CI	(46.9, 64.6)	(44.1, 61.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0590	
	95% CI	(0.8449, 1.3273)	
	Two-sided P-value	0.6187	
Baseline % BSA group: >30-50	Baseline, N	132	121
	Week 26, N	132	121
	Number of Subjects with observed Case, N1 (%)	110 (83.3)	107 (88.4)
	Number of Subjects with NRI, N2 (%)	22 (16.7)	14 (11.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Responders, n (%)	72 (54.5)	53 (43.8)
	95% CI	(46.1, 63.0)	(35.0, 52.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2453	
	95% CI	(0.9651, 1.6069)	
	Two-sided P-value	0.0917	
Baseline % BSA group: >50	Baseline, N	108	111
	Week 26, N	108	111
	Number of Subjects with observed Case, N1 (%)	91 (84.3)	97 (87.4)
	Number of Subjects with NRI, N2 (%)	17 (15.7)	14 (12.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	50 (46.3)	49 (44.1)
	95% CI	(36.9, 55.7)	(34.9, 53.4)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0488	
	95% CI	(0.7835, 1.4039)	
	Two-sided P-value	0.7490	
	P-value of interaction	0.5795	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	172	176
	Week 26, N	172	176
	Number of Subjects with observed Case, N1 (%)	141 (82.0)	160 (90.9)
	Number of Subjects with NRI, N2 (%)	31 (18.0)	16 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	90 (52.3)	83 (47.2)
	95% CI	(44.9, 59.8)	(39.8, 54.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1096	
	95% CI	(0.8979, 1.3711)	
	Two-sided P-value	0.3357	
Prior AD medications: Topical Agents Only	Baseline, N	188	189
	Week 26, N	188	189
	Number of Subjects with observed Case, N1 (%)	158 (84.0)	164 (86.8)
	Number of Subjects with NRI, N2 (%)	30 (16.0)	25 (13.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Responders, n (%)	98 (52.1)	89 (47.1)
	95% CI	(45.0, 59.3)	(40.0, 54.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1070	
	95% CI	(0.9027, 1.3574)	
	Two-sided P-value	0.3287	
	P-value of interaction	0.9876	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	83	105
	Week 26, N	83	105
	Number of Subjects with observed Case, N1 (%)	74 (89.2)	95 (90.5)
	Number of Subjects with NRI, N2 (%)	9 (10.8)	10 (9.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	48 (57.8)	58 (55.2)
	95% CI	(47.2, 68.5)	(45.7, 64.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0469	
	95% CI	(0.8139, 1.3467)	
	Two-sided P-value	0.7210	
Baseline PP-NRS group: >=7	Baseline, N	274	259
	Week 26, N	274	259
	Number of Subjects with observed Case, N1 (%)	225 (82.1)	228 (88.0)
	Number of Subjects with NRI, N2 (%)	49 (17.9)	31 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Responders, n (%)	140 (51.1)	114 (44.0)
	95% CI	(45.2, 57.0)	(38.0, 50.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1608	
	95% CI	(0.9699, 1.3893)	
	Two-sided P-value	0.1038	
	P-value of interaction	0.5129	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Table 14.2.3.1 Abrocitinib
Descriptive Summary of IGA, Absolute Values, Change from Baseline and Percent Change from Baseline up to Week 26 (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD (N=362)						Dupilumab 300mg Q2W (N=365)					
		n (%)	Mean	Median	SD	Q1	Q3	n (%)	Mean	Median	SD	Q1	Q3
Observed Data	Baseline	362 (100.0)	3.4	3.0	0.5	3.0	4.0	365 (100.0)	3.4	3.0	0.5	3.0	4.0
	Week 2	350 (96.7)	2.3	2.0	0.9	2.0	3.0	350 (95.9)	2.7	3.0	0.8	2.0	3.0
	Week 4	341 (94.2)	1.7	2.0	0.9	1.0	2.0	351 (96.2)	2.2	2.0	0.8	2.0	3.0
	Week 8	336 (92.8)	1.5	1.0	0.9	1.0	2.0	348 (95.3)	1.9	2.0	0.9	1.0	3.0
	Week 12	329 (90.9)	1.4	1.0	0.9	1.0	2.0	342 (93.7)	1.8	2.0	0.9	1.0	2.0
	Week 16	325 (89.8)	1.3	1.0	1.0	1.0	2.0	336 (92.1)	1.6	2.0	0.9	1.0	2.0
	Week 20	319 (88.1)	1.2	1.0	0.9	1.0	2.0	333 (91.2)	1.5	1.0	0.9	1.0	2.0
	Week 26	300 (82.9)	1.2	1.0	1.0	0.0	2.0	324 (88.8)	1.4	1.0	0.9	1.0	2.0
Change from Baseline	Week 2	350 (96.7)	-1.1	-1.0	0.8	-2.0	-1.0	350 (95.9)	-0.7	-1.0	0.8	-1.0	0.0
	Week 4	341 (94.2)	-1.7	-2.0	0.9	-2.0	-1.0	351 (96.2)	-1.2	-1.0	0.8	-2.0	-1.0
	Week 8	336 (92.8)	-2.0	-2.0	0.9	-3.0	-1.0	348 (95.3)	-1.5	-1.0	0.9	-2.0	-1.0
	Week 12	329 (90.9)	-2.0	-2.0	1.0	-3.0	-1.0	342 (93.7)	-1.6	-2.0	0.9	-2.0	-1.0
	Week 16	325 (89.8)	-2.1	-2.0	0.9	-3.0	-2.0	336 (92.1)	-1.8	-2.0	1.0	-2.0	-1.0
	Week 20	319 (88.1)	-2.2	-2.0	1.0	-3.0	-2.0	333 (91.2)	-1.9	-2.0	1.0	-3.0	-1.0
	Week 26	300 (82.9)	-2.2	-2.0	1.0	-3.0	-2.0	324 (88.8)	-2.0	-2.0	1.0	-3.0	-1.0
Percent Change from Baseline	Week 2	350 (96.7)	-32.0	-33.3	24.2	-50.0	-25.0	350 (95.9)	-21.6	-25.0	22.6	-33.3	0.0
	Week 4	341 (94.2)	-49.2	-50.0	26.0	-66.7	-33.3	351 (96.2)	-34.4	-33.3	24.4	-50.0	-25.0
	Week 8	336 (92.8)	-57.3	-66.7	26.6	-75.0	-33.3	348 (95.3)	-42.8	-33.3	26.3	-66.7	-25.0
	Week 12	329 (90.9)	-59.6	-66.7	27.6	-75.0	-33.3	342 (93.7)	-47.5	-50.0	25.4	-66.7	-33.3
	Week 16	325 (89.8)	-62.9	-66.7	26.9	-75.0	-50.0	336 (92.1)	-52.5	-50.0	26.3	-66.7	-33.3
	Week 20	319 (88.1)	-65.1	-66.7	26.9	-75.0	-50.0	333 (91.2)	-56.8	-66.7	27.2	-75.0	-33.3

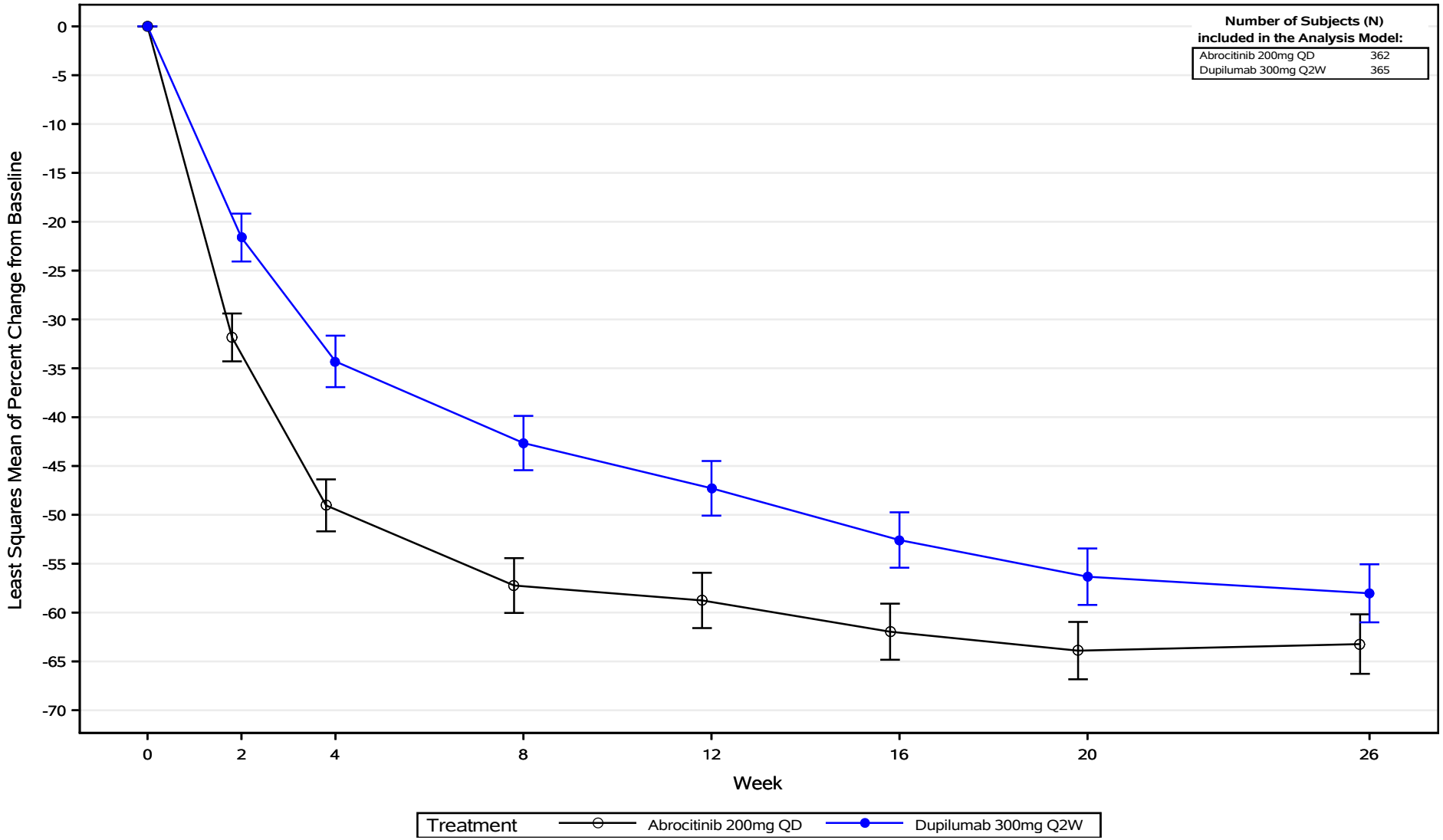
Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
IGA = investigator's global assessment; OD = observed data. Data after dropout or use of rescue therapy was censored.
N = number of subjects in the analysis set.
n = number of subjects in the analysis set with observed data at the specified visit.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:37) Source Data: adad Table Generation: 01SEP2021 (08:26)
Output File: ./nda1_cdisc/B7451050_GBA/adad_s001

Table 14.2.3.1 Abrocitinib
Descriptive Summary of IGA, Absolute Values, Change from Baseline and Percent Change from Baseline up to Week 26 (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD (N=362)						Dupilumab 300mg Q2W (N=365)					
		n (%)	Mean	Median	SD	Q1	Q3	n (%)	Mean	Median	SD	Q1	Q3
Percent Change from Baseline	Week 26	300 (82.9)	-65.3	-66.7	27.9	-100.0	-50.0	324 (88.8)	-58.6	-66.7	26.7	-75.0	-33.3

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
IGA = investigator's global assessment; OD = observed data. Data after dropout or use of rescue therapy was censored.
N = number of subjects in the analysis set.
n = number of subjects in the analysis set with observed data at the specified visit.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:37) Source Data: adad Table Generation: 01SEP2021 (08:26)
Output File: ./nda1_cdisc/B7451050_GBA/adad_s001

Plot of Least Squares Mean of Percent Change from Baseline in IGA at Weeks 2, 4, 8, 12, 16, 20 and 26 - MMRM (FAS, OD)
(Protocol B7451050)



Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Vertical line represented 95% confidence interval.
IGA = investigator's global assessment; OD = observed data. Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction,
baseline disease severity, baseline value and an unstructured covariance matrix.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:37) Source Data: adad Table Generation: 05SEP2021 (22:29)
Output File: ./nda1_cdisc/B7451050_GBA/adad_f401

Table 14.2.3.3 Abrocitinib
Proportion of Subjects Achieving IGA < 2 and >= 2 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 2, Main Analysis) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
Main analysis: NRI after withdrawal or rescue therapy or any missing intermittently	Baseline	N	362	365
	Week 26	N	362	365
		Number of Subjects with observed Case, N1 (%)	300 (82.9)	324 (88.8)
		Number of Subjects with NRI, N2 (%)	62 (17.1)	41 (11.2)
		Number of Subjects Missing Cases without NRI, N3 (%)	0	0
		Responders, n (%)	193 (53.3)	185 (50.7)
		95% CI	(48.2, 58.5)	(45.6, 55.8)
		Abrocitinib - Dupilumab Response Difference		
		Estimate (%)	2.7	
		95% CI	(-4.5, 9.9)	
		Two-sided P-value	0.4612	
		Abrocitinib vs Dupilumab Response Ratio		
		Estimate	1.0535	
		95% CI	(0.9172, 1.2101)	
		Two-sided P-value	0.4608	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; IGA = investigator's global assessment; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response difference, response ratio and odds ratio were calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Table 14.2.3.3 Abrocitinib
Proportion of Subjects Achieving IGA < 2 and >= 2 Points Improvement from Baseline at Week 26 (FAS with Baseline >= 2, Main Analysis) (Protocol B7451050)

			Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Method	**Visit**			
		Abrocitinib vs Dupilumab Odds Ratio		
		Estimate	1.1169	
		95% CI	(0.8327, 1.4981)	
		Two-sided P-value	0.4607	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; IGA = investigator's global assessment; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response difference, response ratio and odds ratio were calculated using Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.
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Table 14.2.3.4 Abrocitinib
Observation Period of IGA Score (FAS, OD)
(Protocol B7451050)

	Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Observation Period of IGA Score (Days)		
n	362	365
Mean (SD)	175.5 (36.81)	179.2 (26.47)
Median (Min, Max)	183.0 (1, 268)	183.0 (1, 221)
Q1, Q3	182.0, 184.0	182.0, 185.0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
SD = Standard Deviation; IGA = investigator's global assessment; OD = Observed Data;
N = number of subjects in the analysis set; n = number of subjects in the analysis set with observed data.
Observation period was defined as last assessment date (on or prior to drop out date if applicable) - date of randomization + 1.
Observation period was assigned as 1 if there was only observed data on or before randomization, and no observed data post randomization.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:37) Source Data: adop Table Generation: 14SEP2021 (02:36)
Output File: ./nda1_cdisc/B7451050_GBA/adad_ob

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	227	246
	Week 26, N	227	246
	Number of Subjects with observed Case, N1 (%)	195 (85.9)	221 (89.8)
	Number of Subjects with NRI, N2 (%)	32 (14.1)	25 (10.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	142 (62.6)	152 (61.8)
	95% CI	(56.3, 68.9)	(55.7, 67.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0124	
	95% CI	(0.8796, 1.1653)	
	Two-sided P-value	0.8636	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Baseline, N	130	118
	Week 26, N	130	118
	Number of Subjects with observed Case, N1 (%)	116 (89.2)	106 (89.8)
	Number of Subjects with NRI, N2 (%)	14 (10.8)	12 (10.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	99 (76.2)	77 (65.3)
	95% CI	(68.8, 83.5)	(56.7, 73.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1670	
	95% CI	(0.9914, 1.3737)	
	Two-sided P-value	0.0634	
	P-value of interaction	0.1958	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	337	353
	Week 26, N	337	353
	Number of Subjects with observed Case, N1 (%)	295 (87.5)	317 (89.8)
	Number of Subjects with NRI, N2 (%)	42 (12.5)	36 (10.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	227 (67.4)	222 (62.9)
	95% CI	(62.4, 72.4)	(57.8, 67.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0711	
	95% CI	(0.9602, 1.1948)	
	Two-sided P-value	0.2182	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Baseline, N	20	11
	Week 26, N	20	11
	Number of Subjects with observed Case, N1 (%)	16 (80.0)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	4 (20.0)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	14 (70.0)	7 (63.6)
	95% CI	(49.9, 90.1)	(35.2, 92.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1000	
	95% CI	(0.6469, 1.8705)	
	Two-sided P-value	0.7249	
	P-value of interaction	0.9232	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	191	204
	Week 26, N	191	204
	Number of Subjects with observed Case, N1 (%)	174 (91.1)	183 (89.7)
	Number of Subjects with NRI, N2 (%)	17 (8.9)	21 (10.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	127 (66.5)	119 (58.3)
	95% CI	(59.8, 73.2)	(51.6, 65.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1399	
	95% CI	(0.9776, 1.3291)	
	Two-sided P-value	0.0948	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Baseline, N	166	160
	Week 26, N	166	160
	Number of Subjects with observed Case, N1 (%)	137 (82.5)	144 (90.0)
	Number of Subjects with NRI, N2 (%)	29 (17.5)	16 (10.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	114 (68.7)	110 (68.8)
	95% CI	(61.6, 75.7)	(61.6, 75.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9989	
	95% CI	(0.8628, 1.1565)	
	Two-sided P-value	0.9883	
	P-value of interaction	0.2229	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	265	247
	Week 26, N	265	247
	Number of Subjects with observed Case, N1 (%)	228 (86.0)	222 (89.9)
	Number of Subjects with NRI, N2 (%)	37 (14.0)	25 (10.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	181 (68.3)	161 (65.2)
	95% CI	(62.7, 73.9)	(59.2, 71.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0479	
	95% CI	(0.9269, 1.1846)	
	Two-sided P-value	0.4549	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	24	26
	Week 26, N	24	26
	Number of Subjects with observed Case, N1 (%)	19 (79.2)	22 (84.6)
	Number of Subjects with NRI, N2 (%)	5 (20.8)	4 (15.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	15 (62.5)	11 (42.3)
	95% CI	(43.1, 81.9)	(23.3, 61.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4773	
	95% CI	(0.8562, 2.5489)	
	Two-sided P-value	0.1609	
Race: ASIAN	Baseline, N	62	83
	Week 26, N	62	83
	Number of Subjects with observed Case, N1 (%)	58 (93.5)	75 (90.4)
	Number of Subjects with NRI, N2 (%)	4 (6.5)	8 (9.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: ASIAN	Responders, n (%)	39 (62.9)	53 (63.9)
	95% CI	(50.9, 74.9)	(53.5, 74.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9851	
	95% CI	(0.7668, 1.2655)	
	Two-sided P-value	0.9064	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (100.0)	4 (50.0)
	95% CI	(54.1, 100.0)	(15.4, 84.6)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.0000	
	95% CI	(1.0002, 3.9992)	
	Two-sided P-value	0.0499	
	P-value of interaction	0.2597	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	174	195
	Week 26, N	174	195
	Number of Subjects with observed Case, N1 (%)	147 (84.5)	172 (88.2)
	Number of Subjects with NRI, N2 (%)	27 (15.5)	23 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	122 (70.1)	120 (61.5)
	95% CI	(63.3, 76.9)	(54.7, 68.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1394	
	95% CI	(0.9832, 1.3203)	
	Two-sided P-value	0.0827	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Baseline, N	148	131
	Week 26, N	148	131
	Number of Subjects with observed Case, N1 (%)	133 (89.9)	122 (93.1)
	Number of Subjects with NRI, N2 (%)	15 (10.1)	9 (6.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	99 (66.9)	84 (64.1)
	95% CI	(59.3, 74.5)	(55.9, 72.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0432	
	95% CI	(0.8792, 1.2378)	
	Two-sided P-value	0.6280	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	16 (94.1)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	1 (5.9)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Asia	Responders, n (%)	7 (41.2)	14 (73.7)
	95% CI	(17.8, 64.6)	(53.9, 93.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.5588	
	95% CI	(0.2981, 1.0477)	
	Two-sided P-value	0.0696	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	15 (83.3)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	3 (16.7)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	13 (72.2)	11 (57.9)
	95% CI	(51.5, 92.9)	(35.7, 80.1)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2475	
	95% CI	(0.7729, 2.0133)	
	Two-sided P-value	0.3653	
	P-value of interaction	0.1556	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	213	219
	Week 26, N	213	219
	Number of Subjects with observed Case, N1 (%)	182 (85.4)	196 (89.5)
	Number of Subjects with NRI, N2 (%)	31 (14.6)	23 (10.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	139 (65.3)	132 (60.3)
	95% CI	(58.9, 71.7)	(53.8, 66.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0827	
	95% CI	(0.9361, 1.2522)	
	Two-sided P-value	0.2844	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Baseline, N	144	145
	Week 26, N	144	145
	Number of Subjects with observed Case, N1 (%)	129 (89.6)	131 (90.3)
	Number of Subjects with NRI, N2 (%)	15 (10.4)	14 (9.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	102 (70.8)	97 (66.9)
	95% CI	(63.4, 78.3)	(59.2, 74.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0588	
	95% CI	(0.9066, 1.2366)	
	Two-sided P-value	0.4703	
	P-value of interaction	0.8374	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	40	51
	Week 26, N	40	51
	Number of Subjects with observed Case, N1 (%)	35 (87.5)	44 (86.3)
	Number of Subjects with NRI, N2 (%)	5 (12.5)	7 (13.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	25 (62.5)	30 (58.8)
	95% CI	(47.5, 77.5)	(45.3, 72.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0625	
	95% CI	(0.7622, 1.4811)	
	Two-sided P-value	0.7206	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	317	313
	Week 26, N	317	313
	Number of Subjects with observed Case, N1 (%)	276 (87.1)	283 (90.4)
	Number of Subjects with NRI, N2 (%)	41 (12.9)	30 (9.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	216 (68.1)	199 (63.6)
	95% CI	(63.0, 73.3)	(58.2, 68.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0717	
	95% CI	(0.9575, 1.1996)	
	Two-sided P-value	0.2282	
	P-value of interaction	0.9615	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	130	136
	Week 26, N	130	136
	Number of Subjects with observed Case, N1 (%)	112 (86.2)	122 (89.7)
	Number of Subjects with NRI, N2 (%)	18 (13.8)	14 (10.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	87 (66.9)	91 (66.9)
	95% CI	(58.8, 75.0)	(59.0, 74.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0002	
	95% CI	(0.8446, 1.1844)	
	Two-sided P-value	0.9984	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Baseline, N	193	183
	Week 26, N	193	183
	Number of Subjects with observed Case, N1 (%)	170 (88.1)	167 (91.3)
	Number of Subjects with NRI, N2 (%)	23 (11.9)	16 (8.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	129 (66.8)	109 (59.6)
	95% CI	(60.2, 73.5)	(52.5, 66.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1222	
	95% CI	(0.9607, 1.3107)	
	Two-sided P-value	0.1458	
Weight (kg): >100	Baseline, N	34	45
	Week 26, N	34	45
	Number of Subjects with observed Case, N1 (%)	29 (85.3)	38 (84.4)
	Number of Subjects with NRI, N2 (%)	5 (14.7)	7 (15.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >100	Responders, n (%)	25 (73.5)	29 (64.4)
	95% CI	(58.7, 88.4)	(50.5, 78.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1410	
	95% CI	(0.8484, 1.5344)	
	Two-sided P-value	0.3829	
	P-value of interaction	0.5631	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	218	219
	Week 26, N	218	219
	Number of Subjects with observed Case, N1 (%)	187 (85.8)	197 (90.0)
	Number of Subjects with NRI, N2 (%)	31 (14.2)	22 (10.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	137 (62.8)	137 (62.6)
	95% CI	(56.4, 69.3)	(56.1, 69.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0046	
	95% CI	(0.8693, 1.1609)	
	Two-sided P-value	0.9505	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Baseline, N	139	145
	Week 26, N	139	145
	Number of Subjects with observed Case, N1 (%)	124 (89.2)	130 (89.7)
	Number of Subjects with NRI, N2 (%)	15 (10.8)	15 (10.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	104 (74.8)	92 (63.4)
	95% CI	(67.6, 82.0)	(55.6, 71.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1792	
	95% CI	(1.0082, 1.3793)	
	Two-sided P-value	0.0392	
	P-value of interaction	0.1407	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	178	183
	Week 26, N	178	183
	Number of Subjects with observed Case, N1 (%)	150 (84.3)	163 (89.1)
	Number of Subjects with NRI, N2 (%)	28 (15.7)	20 (10.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	109 (61.2)	105 (57.4)
	95% CI	(54.1, 68.4)	(50.2, 64.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0673	
	95% CI	(0.8995, 1.2663)	
	Two-sided P-value	0.4557	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Baseline, N	170	173
	Week 26, N	170	173
	Number of Subjects with observed Case, N1 (%)	153 (90.0)	157 (90.8)
	Number of Subjects with NRI, N2 (%)	17 (10.0)	16 (9.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	126 (74.1)	120 (69.4)
	95% CI	(67.5, 80.7)	(62.5, 76.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0685	
	95% CI	(0.9354, 1.2206)	
	Two-sided P-value	0.3288	
	P-value of interaction	0.9914	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	120	133
	Week 26, N	120	133
	Number of Subjects with observed Case, N1 (%)	102 (85.0)	121 (91.0)
	Number of Subjects with NRI, N2 (%)	18 (15.0)	12 (9.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	77 (64.2)	78 (58.6)
	95% CI	(55.6, 72.7)	(50.3, 67.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0941	
	95% CI	(0.8998, 1.3304)	
	Two-sided P-value	0.3673	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Baseline, N	131	121
	Week 26, N	131	121
	Number of Subjects with observed Case, N1 (%)	114 (87.0)	108 (89.3)
	Number of Subjects with NRI, N2 (%)	17 (13.0)	13 (10.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	89 (67.9)	80 (66.1)
	95% CI	(59.9, 75.9)	(57.7, 74.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0276	
	95% CI	(0.8639, 1.2223)	
	Two-sided P-value	0.7586	
Baseline % BSA group: >50	Baseline, N	106	110
	Week 26, N	106	110
	Number of Subjects with observed Case, N1 (%)	95 (89.6)	98 (89.1)
	Number of Subjects with NRI, N2 (%)	11 (10.4)	12 (10.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >50	Responders, n (%)	75 (70.8)	71 (64.5)
	95% CI	(62.1, 79.4)	(55.6, 73.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0962	
	95% CI	(0.9112, 1.3187)	
	Two-sided P-value	0.3301	
	P-value of interaction	0.8503	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	170	175
	Week 26, N	170	175
	Number of Subjects with observed Case, N1 (%)	147 (86.5)	160 (91.4)
	Number of Subjects with NRI, N2 (%)	23 (13.5)	15 (8.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	113 (66.5)	114 (65.1)
	95% CI	(59.4, 73.6)	(58.1, 72.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0204	
	95% CI	(0.8764, 1.1880)	
	Two-sided P-value	0.7949	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Baseline, N	185	189
	Week 26, N	185	189
	Number of Subjects with observed Case, N1 (%)	162 (87.6)	167 (88.4)
	Number of Subjects with NRI, N2 (%)	23 (12.4)	22 (11.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	126 (68.1)	115 (60.8)
	95% CI	(61.4, 74.8)	(53.9, 67.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1193	
	95% CI	(0.9625, 1.3018)	
	Two-sided P-value	0.1434	
	P-value of interaction	0.3973	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	83	105
	Week 26, N	83	105
	Number of Subjects with observed Case, N1 (%)	76 (91.6)	96 (91.4)
	Number of Subjects with NRI, N2 (%)	7 (8.4)	9 (8.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	45 (54.2)	49 (46.7)
	95% CI	(43.5, 64.9)	(37.1, 56.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1618	
	95% CI	(0.8742, 1.5440)	
	Two-sided P-value	0.3014	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Baseline, N	274	259
	Week 26, N	274	259
	Number of Subjects with observed Case, N1 (%)	235 (85.8)	231 (89.2)
	Number of Subjects with NRI, N2 (%)	39 (14.2)	28 (10.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	196 (71.5)	180 (69.5)
	95% CI	(66.2, 76.9)	(63.9, 75.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0293	
	95% CI	(0.9221, 1.1489)	
	Two-sided P-value	0.6070	
	P-value of interaction	0.4363	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	227	243
	Week 26, N	227	243
	Number of Subjects with observed Case, N1 (%)	184 (81.1)	216 (88.9)
	Number of Subjects with NRI, N2 (%)	43 (18.9)	27 (11.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	75 (33.0)	77 (31.7)
	95% CI	(26.9, 39.2)	(25.8, 37.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0427	
	95% CI	(0.8028, 1.3543)	
	Two-sided P-value	0.7541	
Age (years) group: >=40	Baseline, N	131	118
	Week 26, N	131	118
	Number of Subjects with observed Case, N1 (%)	116 (88.5)	105 (89.0)
	Number of Subjects with NRI, N2 (%)	15 (11.5)	13 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	62 (47.3)	37 (31.4)
	95% CI	(38.8, 55.9)	(23.0, 39.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5094	
	95% CI	(1.0935, 2.0835)	
	Two-sided P-value	0.0123	
	P-value of interaction	0.0807	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	337	350
	Week 26, N	337	350
	Number of Subjects with observed Case, N1 (%)	283 (84.0)	311 (88.9)
	Number of Subjects with NRI, N2 (%)	54 (16.0)	39 (11.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	126 (37.4)	111 (31.7)
	95% CI	(32.2, 42.6)	(26.8, 36.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1789	
	95% CI	(0.9588, 1.4496)	
	Two-sided P-value	0.1186	
Age (years) group: >=65	Baseline, N	21	11
	Week 26, N	21	11
	Number of Subjects with observed Case, N1 (%)	17 (81.0)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	4 (19.0)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Responders, n (%)	11 (52.4)	3 (27.3)
	95% CI	(31.0, 73.7)	(1.0, 53.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.9206	
	95% CI	(0.6737, 5.4756)	
	Two-sided P-value	0.2221	
	P-value of interaction	0.3704	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Table 14.2.6.6 Abrocitinib
Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	191	201
	Week 26, N	191	201
	Number of Subjects with observed Case, N1 (%)	168 (88.0)	178 (88.6)
	Number of Subjects with NRI, N2 (%)	23 (12.0)	23 (11.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	70 (36.6)	64 (31.8)
	95% CI	(29.8, 43.5)	(25.4, 38.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1510	
	95% CI	(0.8742, 1.5155)	
	Two-sided P-value	0.3163	
Sex: Female	Baseline, N	167	160
	Week 26, N	167	160
	Number of Subjects with observed Case, N1 (%)	132 (79.0)	143 (89.4)
	Number of Subjects with NRI, N2 (%)	35 (21.0)	17 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	67 (40.1)	50 (31.3)
	95% CI	(32.7, 47.6)	(24.1, 38.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2838	
	95% CI	(0.9556, 1.7247)	
	Two-sided P-value	0.0972	
	P-value of interaction	0.5958	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	267	245
	Week 26, N	267	245
	Number of Subjects with observed Case, N1 (%)	219 (82.0)	218 (89.0)
	Number of Subjects with NRI, N2 (%)	48 (18.0)	27 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	104 (39.0)	83 (33.9)
	95% CI	(33.1, 44.8)	(28.0, 39.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1498	
	95% CI	(0.9130, 1.4479)	
	Two-sided P-value	0.2354	
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	24	25
	Week 26, N	24	25
	Number of Subjects with observed Case, N1 (%)	19 (79.2)	20 (80.0)
	Number of Subjects with NRI, N2 (%)	5 (20.8)	5 (20.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Responders, n (%)	6 (25.0)	9 (36.0)
	95% CI	(7.7, 42.3)	(17.2, 54.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.6944	
	95% CI	(0.2915, 1.6542)	
	Two-sided P-value	0.4103	
Race: ASIAN	Baseline, N	61	83
	Week 26, N	61	83
	Number of Subjects with observed Case, N1 (%)	56 (91.8)	75 (90.4)
	Number of Subjects with NRI, N2 (%)	5 (8.2)	8 (9.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	25 (41.0)	18 (21.7)
	95% CI	(28.6, 53.3)	(12.8, 30.6)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.8898	
	95% CI	(1.1374, 3.1400)	
	Two-sided P-value	0.0140	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	2 (33.3)	4 (50.0)
	95% CI	(0.0, 71.1)	(15.4, 84.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.6667	
	95% CI	(0.1769, 2.5129)	
	Two-sided P-value	0.5492	
	P-value of interaction	0.1397	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	174	191
	Week 26, N	174	191
	Number of Subjects with observed Case, N1 (%)	142 (81.6)	166 (86.9)
	Number of Subjects with NRI, N2 (%)	32 (18.4)	25 (13.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	68 (39.1)	62 (32.5)
	95% CI	(31.8, 46.3)	(25.8, 39.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2039	
	95% CI	(0.9134, 1.5868)	
	Two-sided P-value	0.1878	
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	129 (86.0)	122 (92.4)
	Number of Subjects with NRI, N2 (%)	21 (14.0)	10 (7.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	56 (37.3)	40 (30.3)
	95% CI	(29.6, 45.1)	(22.5, 38.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2320	
	95% CI	(0.8843, 1.7163)	
	Two-sided P-value	0.2174	
Region of enrollment: Asia	Baseline, N	16	19
	Week 26, N	16	19
	Number of Subjects with observed Case, N1 (%)	15 (93.8)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	1 (6.3)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	7 (43.8)	5 (26.3)
	95% CI	(19.4, 68.1)	(6.5, 46.1)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6625	
	95% CI	(0.6525, 4.2360)	
	Two-sided P-value	0.2868	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (33.3)	7 (36.8)
	95% CI	(11.6, 55.1)	(15.2, 58.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9048	
	95% CI	(0.3755, 2.1801)	
	Two-sided P-value	0.8235	
	P-value of interaction	0.8316	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	212	217
	Week 26, N	212	217
	Number of Subjects with observed Case, N1 (%)	175 (82.5)	192 (88.5)
	Number of Subjects with NRI, N2 (%)	37 (17.5)	25 (11.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	81 (38.2)	72 (33.2)
	95% CI	(31.7, 44.7)	(26.9, 39.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1515	
	95% CI	(0.8925, 1.4858)	
	Two-sided P-value	0.2779	
Baseline disease severity: Severe	Baseline, N	146	144
	Week 26, N	146	144
	Number of Subjects with observed Case, N1 (%)	125 (85.6)	129 (89.6)
	Number of Subjects with NRI, N2 (%)	21 (14.4)	15 (10.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	56 (38.4)	42 (29.2)
	95% CI	(30.5, 46.2)	(21.7, 36.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3151	
	95% CI	(0.9481, 1.8241)	
	Two-sided P-value	0.1009	
	P-value of interaction	0.5303	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	39	50
	Week 26, N	39	50
	Number of Subjects with observed Case, N1 (%)	31 (79.5)	43 (86.0)
	Number of Subjects with NRI, N2 (%)	8 (20.5)	7 (14.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	11 (28.2)	13 (26.0)
	95% CI	(14.1, 42.3)	(13.8, 38.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0848	
	95% CI	(0.5468, 2.1523)	
	Two-sided P-value	0.8158	
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	319	311
	Week 26, N	319	311
	Number of Subjects with observed Case, N1 (%)	269 (84.3)	278 (89.4)
	Number of Subjects with NRI, N2 (%)	50 (15.7)	33 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Responders, n (%)	126 (39.5)	101 (32.5)
	95% CI	(34.1, 44.9)	(27.3, 37.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2162	
	95% CI	(0.9858, 1.5005)	
	Two-sided P-value	0.0678	
	P-value of interaction	0.7545	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	130	135
	Week 26, N	130	135
	Number of Subjects with observed Case, N1 (%)	106 (81.5)	121 (89.6)
	Number of Subjects with NRI, N2 (%)	24 (18.5)	14 (10.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	45 (34.6)	43 (31.9)
	95% CI	(26.4, 42.8)	(24.0, 39.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0868	
	95% CI	(0.7723, 1.5293)	
	Two-sided P-value	0.6331	
Weight (kg): >=70 and <=100	Baseline, N	194	181
	Week 26, N	194	181
	Number of Subjects with observed Case, N1 (%)	167 (86.1)	163 (90.1)
	Number of Subjects with NRI, N2 (%)	27 (13.9)	18 (9.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Responders, n (%)	80 (41.2)	56 (30.9)
	95% CI	(34.3, 48.2)	(24.2, 37.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3328	
	95% CI	(1.0125, 1.7546)	
	Two-sided P-value	0.0405	
Weight (kg): >100	Baseline, N	34	45
	Week 26, N	34	45
	Number of Subjects with observed Case, N1 (%)	27 (79.4)	37 (82.2)
	Number of Subjects with NRI, N2 (%)	7 (20.6)	8 (17.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	12 (35.3)	15 (33.3)
	95% CI	(19.2, 51.4)	(19.6, 47.1)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0588	
	95% CI	(0.5726, 1.9579)	
	Two-sided P-value	0.8554	
	P-value of interaction	0.5957	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	220	217
	Week 26, N	220	217
	Number of Subjects with observed Case, N1 (%)	184 (83.6)	192 (88.5)
	Number of Subjects with NRI, N2 (%)	36 (16.4)	25 (11.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	84 (38.2)	70 (32.3)
	95% CI	(31.8, 44.6)	(26.0, 38.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1836	
	95% CI	(0.9165, 1.5287)	
	Two-sided P-value	0.1965	
AD Duration (years) group: >=26	Baseline, N	138	144
	Week 26, N	138	144
	Number of Subjects with observed Case, N1 (%)	116 (84.1)	129 (89.6)
	Number of Subjects with NRI, N2 (%)	22 (15.9)	15 (10.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Responders, n (%)	53 (38.4)	44 (30.6)
	95% CI	(30.3, 46.5)	(23.0, 38.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2569	
	95% CI	(0.9086, 1.7387)	
	Two-sided P-value	0.1672	
	P-value of interaction	0.7757	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	177	181
	Week 26, N	177	181
	Number of Subjects with observed Case, N1 (%)	142 (80.2)	159 (87.8)
	Number of Subjects with NRI, N2 (%)	35 (19.8)	22 (12.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	61 (34.5)	60 (33.1)
	95% CI	(27.5, 41.5)	(26.3, 40.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0396	
	95% CI	(0.7780, 1.3893)	
	Two-sided P-value	0.7927	
Baseline EASI group: >25	Baseline, N	172	172
	Week 26, N	172	172
	Number of Subjects with observed Case, N1 (%)	151 (87.8)	155 (90.1)
	Number of Subjects with NRI, N2 (%)	21 (12.2)	17 (9.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Responders, n (%)	72 (41.9)	49 (28.5)
	95% CI	(34.5, 49.2)	(21.7, 35.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4694	
	95% CI	(1.0939, 1.9738)	
	Two-sided P-value	0.0106	
	P-value of interaction	0.1012	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	120	132
	Week 26, N	120	132
	Number of Subjects with observed Case, N1 (%)	97 (80.8)	119 (90.2)
	Number of Subjects with NRI, N2 (%)	23 (19.2)	13 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	45 (37.5)	45 (34.1)
	95% CI	(28.8, 46.2)	(26.0, 42.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1000	
	95% CI	(0.7900, 1.5317)	
	Two-sided P-value	0.5726	
Baseline % BSA group: >30-50	Baseline, N	131	119
	Week 26, N	131	119
	Number of Subjects with observed Case, N1 (%)	111 (84.7)	105 (88.2)
	Number of Subjects with NRI, N2 (%)	20 (15.3)	14 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Responders, n (%)	51 (38.9)	38 (31.9)
	95% CI	(30.6, 47.3)	(23.6, 40.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2192	
	95% CI	(0.8688, 1.7109)	
	Two-sided P-value	0.2517	
Baseline % BSA group: >50	Baseline, N	107	110
	Week 26, N	107	110
	Number of Subjects with observed Case, N1 (%)	92 (86.0)	97 (88.2)
	Number of Subjects with NRI, N2 (%)	15 (14.0)	13 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	41 (38.3)	31 (28.2)
	95% CI	(29.1, 47.5)	(19.8, 36.6)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3597	
	95% CI	(0.9269, 1.9944)	
	Two-sided P-value	0.1160	
	P-value of interaction	0.7131	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	171	175
	Week 26, N	171	175
	Number of Subjects with observed Case, N1 (%)	140 (81.9)	160 (91.4)
	Number of Subjects with NRI, N2 (%)	31 (18.1)	15 (8.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	57 (33.3)	50 (28.6)
	95% CI	(26.3, 40.4)	(21.9, 35.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1667	
	95% CI	(0.8506, 1.6001)	
	Two-sided P-value	0.3389	
Prior AD medications: Topical Agents Only	Baseline, N	185	186
	Week 26, N	185	186
	Number of Subjects with observed Case, N1 (%)	158 (85.4)	161 (86.6)
	Number of Subjects with NRI, N2 (%)	27 (14.6)	25 (13.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Responders, n (%)	78 (42.2)	64 (34.4)
	95% CI	(35.0, 49.3)	(27.6, 41.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2253	
	95% CI	(0.9443, 1.5900)	
	Two-sided P-value	0.1263	
	P-value of interaction	0.8143	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	82	103
	Week 26, N	82	103
	Number of Subjects with observed Case, N1 (%)	74 (90.2)	93 (90.3)
	Number of Subjects with NRI, N2 (%)	8 (9.8)	10 (9.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	37 (45.1)	31 (30.1)
	95% CI	(34.4, 55.9)	(21.2, 39.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4992	
	95% CI	(1.0263, 2.1900)	
	Two-sided P-value	0.0362	
Baseline PP-NRS group: >=7	Baseline, N	272	257
	Week 26, N	272	257
	Number of Subjects with observed Case, N1 (%)	224 (82.4)	227 (88.3)
	Number of Subjects with NRI, N2 (%)	48 (17.6)	30 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Responders, n (%)	99 (36.4)	83 (32.3)
	95% CI	(30.7, 42.1)	(26.6, 38.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1270	
	95% CI	(0.8895, 1.4279)	
	Two-sided P-value	0.3221	
	P-value of interaction	0.2106	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	216	234
	Week 26, N	216	234
	Number of Subjects with observed Case, N1 (%)	174 (80.6)	208 (88.9)
	Number of Subjects with NRI, N2 (%)	42 (19.4)	26 (11.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	147 (68.1)	183 (78.2)
	95% CI	(61.8, 74.3)	(72.9, 83.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8702	
	95% CI	(0.7767, 0.9750)	
	Two-sided P-value	0.0165	
Age (years) group: >=40	Baseline, N	120	111
	Week 26, N	120	111
	Number of Subjects with observed Case, N1 (%)	107 (89.2)	99 (89.2)
	Number of Subjects with NRI, N2 (%)	13 (10.8)	12 (10.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	96 (80.0)	87 (78.4)
	95% CI	(72.8, 87.2)	(70.7, 86.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0207	
	95% CI	(0.8940, 1.1653)	
	Two-sided P-value	0.7619	
	P-value of interaction	0.0733	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	319	335
	Week 26, N	319	335
	Number of Subjects with observed Case, N1 (%)	267 (83.7)	298 (89.0)
	Number of Subjects with NRI, N2 (%)	52 (16.3)	37 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	230 (72.1)	261 (77.9)
	95% CI	(67.2, 77.0)	(73.5, 82.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9254	
	95% CI	(0.8467, 1.0115)	
	Two-sided P-value	0.0877	
Age (years) group: >=65	Baseline, N	17	10
	Week 26, N	17	10
	Number of Subjects with observed Case, N1 (%)	14 (82.4)	9 (90.0)
	Number of Subjects with NRI, N2 (%)	3 (17.6)	1 (10.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Responders, n (%)	13 (76.5)	9 (90.0)
	95% CI	(56.3, 96.6)	(71.4, 100.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8497	
	95% CI	(0.6078, 1.1878)	
	Two-sided P-value	0.3405	
	P-value of interaction	0.6291	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	178	191
	Week 26, N	178	191
	Number of Subjects with observed Case, N1 (%)	156 (87.6)	170 (89.0)
	Number of Subjects with NRI, N2 (%)	22 (12.4)	21 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	132 (74.2)	146 (76.4)
	95% CI	(67.7, 80.6)	(70.4, 82.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9701	
	95% CI	(0.8629, 1.0907)	
	Two-sided P-value	0.6120	
Sex: Female	Baseline, N	158	154
	Week 26, N	158	154
	Number of Subjects with observed Case, N1 (%)	125 (79.1)	137 (89.0)
	Number of Subjects with NRI, N2 (%)	33 (20.9)	17 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	111 (70.3)	124 (80.5)
	95% CI	(63.1, 77.4)	(74.3, 86.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8725	
	95% CI	(0.7678, 0.9914)	
	Two-sided P-value	0.0364	
	P-value of interaction	0.2304	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	251	235
	Week 26, N	251	235
	Number of Subjects with observed Case, N1 (%)	206 (82.1)	210 (89.4)
	Number of Subjects with NRI, N2 (%)	45 (17.9)	25 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	178 (70.9)	185 (78.7)
	95% CI	(65.3, 76.5)	(73.5, 84.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9008	
	95% CI	(0.8123, 0.9990)	
	Two-sided P-value	0.0478	
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	23	22
	Week 26, N	23	22
	Number of Subjects with observed Case, N1 (%)	18 (78.3)	17 (77.3)
	Number of Subjects with NRI, N2 (%)	5 (21.7)	5 (22.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Responders, n (%)	16 (69.6)	15 (68.2)
	95% CI	(50.8, 88.4)	(48.7, 87.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0203	
	95% CI	(0.6886, 1.5117)	
	Two-sided P-value	0.9202	
Race: ASIAN	Baseline, N	56	80
	Week 26, N	56	80
	Number of Subjects with observed Case, N1 (%)	51 (91.1)	72 (90.0)
	Number of Subjects with NRI, N2 (%)	5 (8.9)	8 (10.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	45 (80.4)	65 (81.3)
	95% CI	(70.0, 90.8)	(72.7, 89.8)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9890	
	95% CI	(0.8370, 1.1686)	
	Two-sided P-value	0.8967	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	4 (66.7)	5 (62.5)
	95% CI	(28.9, 100.0)	(29.0, 96.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0667	
	95% CI	(0.4890, 2.3267)	
	Two-sided P-value	0.8712	
	P-value of interaction	0.7485	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	161	182
	Week 26, N	161	182
	Number of Subjects with observed Case, N1 (%)	131 (81.4)	158 (86.8)
	Number of Subjects with NRI, N2 (%)	30 (18.6)	24 (13.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	114 (70.8)	138 (75.8)
	95% CI	(63.8, 77.8)	(69.6, 82.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9338	
	95% CI	(0.8211, 1.0621)	
	Two-sided P-value	0.2972	
Region of enrollment: Europe	Baseline, N	142	126
	Week 26, N	142	126
	Number of Subjects with observed Case, N1 (%)	122 (85.9)	117 (92.9)
	Number of Subjects with NRI, N2 (%)	20 (14.1)	9 (7.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	104 (73.2)	102 (81.0)
	95% CI	(66.0, 80.5)	(74.1, 87.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9047	
	95% CI	(0.7940, 1.0309)	
	Two-sided P-value	0.1330	
Region of enrollment: Asia	Baseline, N	15	19
	Week 26, N	15	19
	Number of Subjects with observed Case, N1 (%)	14 (93.3)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	1 (6.7)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	12 (80.0)	18 (94.7)
	95% CI	(59.8, 100.0)	(84.7, 100.0)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8444	
	95% CI	(0.6418, 1.1110)	
	Two-sided P-value	0.2271	
Region of enrollment: Latin America	Baseline, N	18	18
	Week 26, N	18	18
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	14 (77.8)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (22.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	13 (72.2)	12 (66.7)
	95% CI	(51.5, 92.9)	(44.9, 88.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0833	
	95% CI	(0.7016, 1.6729)	
	Two-sided P-value	0.7181	
	P-value of interaction	0.7941	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	197	204
	Week 26, N	197	204
	Number of Subjects with observed Case, N1 (%)	161 (81.7)	181 (88.7)
	Number of Subjects with NRI, N2 (%)	36 (18.3)	23 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	137 (69.5)	153 (75.0)
	95% CI	(63.1, 76.0)	(69.1, 80.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9272	
	95% CI	(0.8210, 1.0473)	
	Two-sided P-value	0.2239	
Baseline disease severity: Severe	Baseline, N	139	141
	Week 26, N	139	141
	Number of Subjects with observed Case, N1 (%)	120 (86.3)	126 (89.4)
	Number of Subjects with NRI, N2 (%)	19 (13.7)	15 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	106 (76.3)	117 (83.0)
	95% CI	(69.2, 83.3)	(76.8, 89.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9190	
	95% CI	(0.8158, 1.0353)	
	Two-sided P-value	0.1647	
	P-value of interaction	0.9183	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	37	50
	Week 26, N	37	50
	Number of Subjects with observed Case, N1 (%)	29 (78.4)	43 (86.0)
	Number of Subjects with NRI, N2 (%)	8 (21.6)	7 (14.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	25 (67.6)	36 (72.0)
	95% CI	(52.5, 82.7)	(59.6, 84.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9384	
	95% CI	(0.7076, 1.2446)	
	Two-sided P-value	0.6592	
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	299	295
	Week 26, N	299	295
	Number of Subjects with observed Case, N1 (%)	252 (84.3)	264 (89.5)
	Number of Subjects with NRI, N2 (%)	47 (15.7)	31 (10.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Responders, n (%)	218 (72.9)	234 (79.3)
	95% CI	(67.9, 77.9)	(74.7, 83.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9192	
	95% CI	(0.8397, 1.0061)	
	Two-sided P-value	0.0675	
	P-value of interaction	0.8908	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	122	129
	Week 26, N	122	129
	Number of Subjects with observed Case, N1 (%)	100 (82.0)	115 (89.1)
	Number of Subjects with NRI, N2 (%)	22 (18.0)	14 (10.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	83 (68.0)	104 (80.6)
	95% CI	(59.8, 76.3)	(73.8, 87.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8439	
	95% CI	(0.7277, 0.9786)	
	Two-sided P-value	0.0247	
Weight (kg): >=70 and <=100	Baseline, N	183	174
	Week 26, N	183	174
	Number of Subjects with observed Case, N1 (%)	157 (85.8)	157 (90.2)
	Number of Subjects with NRI, N2 (%)	26 (14.2)	17 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Responders, n (%)	139 (76.0)	133 (76.4)
	95% CI	(69.8, 82.1)	(70.1, 82.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9937	
	95% CI	(0.8849, 1.1159)	
	Two-sided P-value	0.9151	
Weight (kg): >100	Baseline, N	31	42
	Week 26, N	31	42
	Number of Subjects with observed Case, N1 (%)	24 (77.4)	35 (83.3)
	Number of Subjects with NRI, N2 (%)	7 (22.6)	7 (16.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	21 (67.7)	33 (78.6)
	95% CI	(51.3, 84.2)	(66.2, 91.0)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8622	
	95% CI	(0.6453, 1.1519)	
	Two-sided P-value	0.3158	
	P-value of interaction	0.2055	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	205	204
	Week 26, N	205	204
	Number of Subjects with observed Case, N1 (%)	171 (83.4)	181 (88.7)
	Number of Subjects with NRI, N2 (%)	34 (16.6)	23 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	146 (71.2)	162 (79.4)
	95% CI	(65.0, 77.4)	(73.9, 85.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8968	
	95% CI	(0.8021, 1.0027)	
	Two-sided P-value	0.0559	
AD Duration (years) group: >=26	Baseline, N	131	141
	Week 26, N	131	141
	Number of Subjects with observed Case, N1 (%)	110 (84.0)	126 (89.4)
	Number of Subjects with NRI, N2 (%)	21 (16.0)	15 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Responders, n (%)	97 (74.0)	108 (76.6)
	95% CI	(66.5, 81.6)	(69.6, 83.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9667	
	95% CI	(0.8435, 1.1080)	
	Two-sided P-value	0.6266	
	P-value of interaction	0.4041	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	163	171
	Week 26, N	163	171
	Number of Subjects with observed Case, N1 (%)	130 (79.8)	151 (88.3)
	Number of Subjects with NRI, N2 (%)	33 (20.2)	20 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	108 (66.3)	133 (77.8)
	95% CI	(59.0, 73.5)	(71.5, 84.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8519	
	95% CI	(0.7438, 0.9757)	
	Two-sided P-value	0.0206	
Baseline EASI group: >25	Baseline, N	165	167
	Week 26, N	165	167
	Number of Subjects with observed Case, N1 (%)	145 (87.9)	150 (89.8)
	Number of Subjects with NRI, N2 (%)	20 (12.1)	17 (10.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Responders, n (%)	130 (78.8)	131 (78.4)
	95% CI	(72.6, 85.0)	(72.2, 84.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0044	
	95% CI	(0.8978, 1.1237)	
	Two-sided P-value	0.9389	
	P-value of interaction	0.0668	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	109	125
	Week 26, N	109	125
	Number of Subjects with observed Case, N1 (%)	88 (80.7)	112 (89.6)
	Number of Subjects with NRI, N2 (%)	21 (19.3)	13 (10.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	73 (67.0)	98 (78.4)
	95% CI	(58.1, 75.8)	(71.2, 85.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8542	
	95% CI	(0.7274, 1.0032)	
	Two-sided P-value	0.0548	
Baseline % BSA group: >30-50	Baseline, N	124	114
	Week 26, N	124	114
	Number of Subjects with observed Case, N1 (%)	104 (83.9)	102 (89.5)
	Number of Subjects with NRI, N2 (%)	20 (16.1)	12 (10.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Responders, n (%)	92 (74.2)	91 (79.8)
	95% CI	(66.5, 81.9)	(72.5, 87.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9295	
	95% CI	(0.8089, 1.0680)	
	Two-sided P-value	0.3019	
Baseline % BSA group: >50	Baseline, N	103	106
	Week 26, N	103	106
	Number of Subjects with observed Case, N1 (%)	89 (86.4)	93 (87.7)
	Number of Subjects with NRI, N2 (%)	14 (13.6)	13 (12.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	78 (75.7)	81 (76.4)
	95% CI	(67.4, 84.0)	(68.3, 84.5)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9910	
	95% CI	(0.8512, 1.1538)	
	Two-sided P-value	0.9074	
	P-value of interaction	0.4202	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	163	168
	Week 26, N	163	168
	Number of Subjects with observed Case, N1 (%)	133 (81.6)	154 (91.7)
	Number of Subjects with NRI, N2 (%)	30 (18.4)	14 (8.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	117 (71.8)	135 (80.4)
	95% CI	(64.9, 78.7)	(74.3, 86.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8933	
	95% CI	(0.7908, 1.0090)	
	Two-sided P-value	0.0695	
Prior AD medications: Topical Agents Only	Baseline, N	171	177
	Week 26, N	171	177
	Number of Subjects with observed Case, N1 (%)	146 (85.4)	153 (86.4)
	Number of Subjects with NRI, N2 (%)	25 (14.6)	24 (13.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Responders, n (%)	124 (72.5)	135 (76.3)
	95% CI	(65.8, 79.2)	(70.0, 82.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9507	
	95% CI	(0.8402, 1.0758)	
	Two-sided P-value	0.4230	
	P-value of interaction	0.4812	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	71	96
	Week 26, N	71	96
	Number of Subjects with observed Case, N1 (%)	63 (88.7)	87 (90.6)
	Number of Subjects with NRI, N2 (%)	8 (11.3)	9 (9.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	49 (69.0)	74 (77.1)
	95% CI	(58.3, 79.8)	(68.7, 85.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8953	
	95% CI	(0.7402, 1.0829)	
	Two-sided P-value	0.2546	
Baseline PP-NRS group: >=7	Baseline, N	262	248
	Week 26, N	262	248
	Number of Subjects with observed Case, N1 (%)	216 (82.4)	219 (88.3)
	Number of Subjects with NRI, N2 (%)	46 (17.6)	29 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI >= 5 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 5, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Responders, n (%)	192 (73.3)	196 (79.0)
	95% CI	(67.9, 78.6)	(74.0, 84.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9272	
	95% CI	(0.8413, 1.0219)	
	Two-sided P-value	0.1279	
	P-value of interaction	0.7479	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	226	246
	Week 26, N	226	246
	Number of Subjects with observed Case, N1 (%)	183 (81.0)	220 (89.4)
	Number of Subjects with NRI, N2 (%)	43 (19.0)	26 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	10 (4.4)	4 (1.6)
	95% CI	(1.7, 7.1)	(0.0, 3.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.7212	
	95% CI	(0.8656, 8.5546)	
	Two-sided P-value	0.0867	
Age (years) group: >=40	Baseline, N	131	115
	Week 26, N	131	115
	Number of Subjects with observed Case, N1 (%)	116 (88.5)	101 (87.8)
	Number of Subjects with NRI, N2 (%)	15 (11.5)	14 (12.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	3 (2.3)	2 (1.7)
	95% CI	(0.0, 4.9)	(0.0, 4.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3168	
	95% CI	(0.2239, 7.7429)	
	Two-sided P-value	0.7608	
	P-value of interaction	0.5001	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	336	350
	Week 26, N	336	350
	Number of Subjects with observed Case, N1 (%)	282 (83.9)	311 (88.9)
	Number of Subjects with NRI, N2 (%)	54 (16.1)	39 (11.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	13 (3.9)	6 (1.7)
	95% CI	(1.8, 5.9)	(0.4, 3.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.2569	
	95% CI	(0.8679, 5.8691)	
	Two-sided P-value	0.0950	
Age (years) group: >=65	Baseline, N	21	11
	Week 26, N	21	11
	Number of Subjects with observed Case, N1 (%)	17 (81.0)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	4 (19.0)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Responders, n (%)	0	0
	95% CI	(0.0, 16.1)	(0.0, 28.5)
	P-value of interaction	0.4773	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	192	202
	Week 26, N	192	202
	Number of Subjects with observed Case, N1 (%)	169 (88.0)	178 (88.1)
	Number of Subjects with NRI, N2 (%)	23 (12.0)	24 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (3.1)	2 (1.0)
	95% CI	(0.7, 5.6)	(0.0, 2.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	3.1563	
	95% CI	(0.6449, 15.4475)	
	Two-sided P-value	0.1560	
Sex: Female	Baseline, N	165	159
	Week 26, N	165	159
	Number of Subjects with observed Case, N1 (%)	130 (78.8)	143 (89.9)
	Number of Subjects with NRI, N2 (%)	35 (21.2)	16 (10.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	7 (4.2)	4 (2.5)
	95% CI	(1.2, 7.3)	(0.1, 4.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6864	
	95% CI	(0.5034, 5.6496)	
	Two-sided P-value	0.3969	
	P-value of interaction	0.5382	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	264	245
	Week 26, N	264	245
	Number of Subjects with observed Case, N1 (%)	217 (82.2)	217 (88.6)
	Number of Subjects with NRI, N2 (%)	47 (17.8)	28 (11.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (2.3)	6 (2.4)
	95% CI	(0.5, 4.1)	(0.5, 4.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9280	
	95% CI	(0.3034, 2.8390)	
	Two-sided P-value	0.8958	
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	25	25
	Week 26, N	25	25
	Number of Subjects with observed Case, N1 (%)	19 (76.0)	21 (84.0)
	Number of Subjects with NRI, N2 (%)	6 (24.0)	4 (16.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Responders, n (%)	2 (8.0)	0
	95% CI	(0.0, 18.6)	(0.0, 13.7)
Race: ASIAN	Baseline, N	62	83
	Week 26, N	62	83
	Number of Subjects with observed Case, N1 (%)	57 (91.9)	75 (90.4)
	Number of Subjects with NRI, N2 (%)	5 (8.1)	8 (9.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	4 (6.5)	0
	95% CI	(0.3, 12.6)	(0.0, 4.3)
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	1 (16.7)	0
	95% CI	(0.0, 46.5)	(0.0, 36.9)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	P-value of interaction	0.3886	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	192
	Week 26, N	177	192
	Number of Subjects with observed Case, N1 (%)	144 (81.4)	167 (87.0)
	Number of Subjects with NRI, N2 (%)	33 (18.6)	25 (13.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (3.4)	0
	95% CI	(0.7, 6.1)	(0.0, 1.9)
Region of enrollment: Europe	Baseline, N	145	131
	Week 26, N	145	131
	Number of Subjects with observed Case, N1 (%)	125 (86.2)	121 (92.4)
	Number of Subjects with NRI, N2 (%)	20 (13.8)	10 (7.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	5 (3.4)	6 (4.6)
	95% CI	(0.5, 6.4)	(1.0, 8.2)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.7529	
	95% CI	(0.2353, 2.4090)	
	Two-sided P-value	0.6324	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	16 (94.1)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	1 (5.9)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	2 (11.8)	0
	95% CI	(0.0, 27.1)	(0.0, 17.6)
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Latin America	95% CI	(0.0, 18.5)	(0.0, 17.6)
	P-value of interaction	0.2624	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	216	220
	Week 26, N	216	220
	Number of Subjects with observed Case, N1 (%)	178 (82.4)	195 (88.6)
	Number of Subjects with NRI, N2 (%)	38 (17.6)	25 (11.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	11 (5.1)	6 (2.7)
	95% CI	(2.2, 8.0)	(0.6, 4.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.8673	
	95% CI	(0.7030, 4.9596)	
	Two-sided P-value	0.2102	
Baseline disease severity: Severe	Baseline, N	141	141
	Week 26, N	141	141
	Number of Subjects with observed Case, N1 (%)	121 (85.8)	126 (89.4)
	Number of Subjects with NRI, N2 (%)	20 (14.2)	15 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	2 (1.4)	0
	95% CI	(0.0, 3.4)	(0.0, 2.6)
	P-value of interaction	0.6435	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	38	51
	Week 26, N	38	51
	Number of Subjects with observed Case, N1 (%)	31 (81.6)	44 (86.3)
	Number of Subjects with NRI, N2 (%)	7 (18.4)	7 (13.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	1 (2.6)	1 (2.0)
	95% CI	(0.0, 7.7)	(0.0, 5.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3421	
	95% CI	(0.0867, 20.7810)	
	Two-sided P-value	0.8333	
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	319	310
	Week 26, N	319	310
	Number of Subjects with observed Case, N1 (%)	268 (84.0)	277 (89.4)
	Number of Subjects with NRI, N2 (%)	51 (16.0)	33 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Responders, n (%)	12 (3.8)	5 (1.6)
	95% CI	(1.7, 5.8)	(0.2, 3.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.3323	
	95% CI	(0.8314, 6.5427)	
	Two-sided P-value	0.1076	
	P-value of interaction	0.7114	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	129	135
	Week 26, N	129	135
	Number of Subjects with observed Case, N1 (%)	106 (82.2)	121 (89.6)
	Number of Subjects with NRI, N2 (%)	23 (17.8)	14 (10.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	5 (3.9)	3 (2.2)
	95% CI	(0.5, 7.2)	(0.0, 4.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.7442	
	95% CI	(0.4255, 7.1503)	
	Two-sided P-value	0.4396	
Weight (kg): >=70 and <=100	Baseline, N	195	182
	Week 26, N	195	182
	Number of Subjects with observed Case, N1 (%)	167 (85.6)	165 (90.7)
	Number of Subjects with NRI, N2 (%)	28 (14.4)	17 (9.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Responders, n (%)	6 (3.1)	3 (1.6)
	95% CI	(0.7, 5.5)	(0.0, 3.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.8667	
	95% CI	(0.4738, 7.3541)	
	Two-sided P-value	0.3723	
Weight (kg): >100	Baseline, N	33	44
	Week 26, N	33	44
	Number of Subjects with observed Case, N1 (%)	26 (78.8)	35 (79.5)
	Number of Subjects with NRI, N2 (%)	7 (21.2)	9 (20.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	2 (6.1)	0
	95% CI	(0.0, 14.2)	(0.0, 8.0)
	P-value of interaction	0.7993	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	219	219
	Week 26, N	219	219
	Number of Subjects with observed Case, N1 (%)	183 (83.6)	195 (89.0)
	Number of Subjects with NRI, N2 (%)	36 (16.4)	24 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	11 (5.0)	3 (1.4)
	95% CI	(2.1, 7.9)	(0.0, 2.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	3.6667	
	95% CI	(1.0372, 12.9626)	
	Two-sided P-value	0.0437	
AD Duration (years) group: >=26	Baseline, N	138	142
	Week 26, N	138	142
	Number of Subjects with observed Case, N1 (%)	116 (84.1)	126 (88.7)
	Number of Subjects with NRI, N2 (%)	22 (15.9)	16 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Responders, n (%)	2 (1.4)	3 (2.1)
	95% CI	(0.0, 3.4)	(0.0, 4.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.6860	
	95% CI	(0.1164, 4.0426)	
	Two-sided P-value	0.6771	
	P-value of interaction	0.1313	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	180	183
	Week 26, N	180	183
	Number of Subjects with observed Case, N1 (%)	144 (80.0)	161 (88.0)
	Number of Subjects with NRI, N2 (%)	36 (20.0)	22 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	10 (5.6)	3 (1.6)
	95% CI	(2.2, 8.9)	(0.0, 3.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	3.3889	
	95% CI	(0.9482, 12.1120)	
	Two-sided P-value	0.0604	
Baseline EASI group: >25	Baseline, N	168	170
	Week 26, N	168	170
	Number of Subjects with observed Case, N1 (%)	148 (88.1)	153 (90.0)
	Number of Subjects with NRI, N2 (%)	20 (11.9)	17 (10.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Responders, n (%)	2 (1.2)	3 (1.8)
	95% CI	(0.0, 2.8)	(0.0, 3.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.6746	
	95% CI	(0.1142, 3.9861)	
	Two-sided P-value	0.6641	
	P-value of interaction	0.1478	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	122	133
	Week 26, N	122	133
	Number of Subjects with observed Case, N1 (%)	99 (81.1)	120 (90.2)
	Number of Subjects with NRI, N2 (%)	23 (18.9)	13 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	7 (5.7)	3 (2.3)
	95% CI	(1.6, 9.9)	(0.0, 4.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.5437	
	95% CI	(0.6728, 9.6179)	
	Two-sided P-value	0.1689	
Baseline % BSA group: >30-50	Baseline, N	129	120
	Week 26, N	129	120
	Number of Subjects with observed Case, N1 (%)	109 (84.5)	106 (88.3)
	Number of Subjects with NRI, N2 (%)	20 (15.5)	14 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Responders, n (%)	5 (3.9)	2 (1.7)
	95% CI	(0.5, 7.2)	(0.0, 4.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.3256	
	95% CI	(0.4598, 11.7616)	
	Two-sided P-value	0.3075	
Baseline % BSA group: >50	Baseline, N	106	108
	Week 26, N	106	108
	Number of Subjects with observed Case, N1 (%)	91 (85.8)	95 (88.0)
	Number of Subjects with NRI, N2 (%)	15 (14.2)	13 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	1 (0.9)	1 (0.9)
	95% CI	(0.0, 2.8)	(0.0, 2.7)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0189	
	95% CI	(0.0646, 16.0790)	
	Two-sided P-value	0.9894	
	P-value of interaction	0.8397	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	169	174
	Week 26, N	169	174
	Number of Subjects with observed Case, N1 (%)	139 (82.2)	158 (90.8)
	Number of Subjects with NRI, N2 (%)	30 (17.8)	16 (9.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (3.6)	4 (2.3)
	95% CI	(0.8, 6.3)	(0.1, 4.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5444	
	95% CI	(0.4437, 5.3760)	
	Two-sided P-value	0.4946	
Prior AD medications: Topical Agents Only	Baseline, N	187	187
	Week 26, N	187	187
	Number of Subjects with observed Case, N1 (%)	159 (85.0)	163 (87.2)
	Number of Subjects with NRI, N2 (%)	28 (15.0)	24 (12.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Responders, n (%)	7 (3.7)	2 (1.1)
	95% CI	(1.0, 6.5)	(0.0, 2.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	3.5000	
	95% CI	(0.7367, 16.6283)	
	Two-sided P-value	0.1151	
	P-value of interaction	0.4218	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	83	105
	Week 26, N	83	105
	Number of Subjects with observed Case, N1 (%)	75 (90.4)	95 (90.5)
	Number of Subjects with NRI, N2 (%)	8 (9.6)	10 (9.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	7 (8.4)	5 (4.8)
	95% CI	(2.5, 14.4)	(0.7, 8.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.7711	
	95% CI	(0.5831, 5.3792)	
	Two-sided P-value	0.3133	
Baseline PP-NRS group: >=7	Baseline, N	269	255
	Week 26, N	269	255
	Number of Subjects with observed Case, N1 (%)	222 (82.5)	225 (88.2)
	Number of Subjects with NRI, N2 (%)	47 (17.5)	30 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with EQ-5D VAS Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup (FAS with Baseline >= 15, NRI) (Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Responders, n (%)	6 (2.2)	1 (0.4)
	95% CI	(0.5, 4.0)	(0.0, 1.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	5.6877	
	95% CI	(0.6895, 46.9166)	
	Two-sided P-value	0.1064	
	P-value of interaction	0.3376	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score.; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	226	246
	Week 26, N	226	246
	Number of Subjects with observed Case, N1 (%)	182 (80.5)	217 (88.2)
	Number of Subjects with NRI, N2 (%)	44 (19.5)	29 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	56 (24.8)	47 (19.1)
	95% CI	(19.2, 30.4)	(14.2, 24.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2969	
	95% CI	(0.9203, 1.8278)	
	Two-sided P-value	0.1375	
Age (years) group: >=40	Baseline, N	132	117
	Week 26, N	132	117
	Number of Subjects with observed Case, N1 (%)	117 (88.6)	103 (88.0)
	Number of Subjects with NRI, N2 (%)	15 (11.4)	14 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	50 (37.9)	22 (18.8)
	95% CI	(29.6, 46.2)	(11.7, 25.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.0145	
	95% CI	(1.3035, 3.1133)	
	Two-sided P-value	0.0016	
	P-value of interaction	0.1194	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	337	352
	Week 26, N	337	352
	Number of Subjects with observed Case, N1 (%)	282 (83.7)	310 (88.1)
	Number of Subjects with NRI, N2 (%)	55 (16.3)	42 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	96 (28.5)	68 (19.3)
	95% CI	(23.7, 33.3)	(15.2, 23.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4746	
	95% CI	(1.1230, 1.9363)	
	Two-sided P-value	0.0052	
Age (years) group: >=65	Baseline, N	21	11
	Week 26, N	21	11
	Number of Subjects with observed Case, N1 (%)	17 (81.0)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	4 (19.0)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Responders, n (%)	10 (47.6)	1 (9.1)
	95% CI	(26.3, 69.0)	(0.0, 26.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	5.2381	
	95% CI	(0.7665, 35.7945)	
	Two-sided P-value	0.0913	
	P-value of interaction	0.2006	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	190	202
	Week 26, N	190	202
	Number of Subjects with observed Case, N1 (%)	167 (87.9)	178 (88.1)
	Number of Subjects with NRI, N2 (%)	23 (12.1)	24 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	54 (28.4)	34 (16.8)
	95% CI	(22.0, 34.8)	(11.7, 22.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6885	
	95% CI	(1.1540, 2.4707)	
	Two-sided P-value	0.0070	
Sex: Female	Baseline, N	168	161
	Week 26, N	168	161
	Number of Subjects with observed Case, N1 (%)	132 (78.6)	142 (88.2)
	Number of Subjects with NRI, N2 (%)	36 (21.4)	19 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	52 (31.0)	35 (21.7)
	95% CI	(24.0, 37.9)	(15.4, 28.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4238	
	95% CI	(0.9835, 2.0613)	
	Two-sided P-value	0.0613	
	P-value of interaction	0.5289	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	268	247
	Week 26, N	268	247
	Number of Subjects with observed Case, N1 (%)	220 (82.1)	217 (87.9)
	Number of Subjects with NRI, N2 (%)	48 (17.9)	30 (12.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	81 (30.2)	47 (19.0)
	95% CI	(24.7, 35.7)	(14.1, 23.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5884	
	95% CI	(1.1591, 2.1766)	
	Two-sided P-value	0.0040	
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	25	25
	Week 26, N	25	25
	Number of Subjects with observed Case, N1 (%)	19 (76.0)	20 (80.0)
	Number of Subjects with NRI, N2 (%)	6 (24.0)	5 (20.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Responders, n (%)	9 (36.0)	6 (24.0)
	95% CI	(17.2, 54.8)	(7.3, 40.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5000	
	95% CI	(0.6274, 3.5862)	
	Two-sided P-value	0.3619	
Race: ASIAN	Baseline, N	59	83
	Week 26, N	59	83
	Number of Subjects with observed Case, N1 (%)	54 (91.5)	75 (90.4)
	Number of Subjects with NRI, N2 (%)	5 (8.5)	8 (9.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	14 (23.7)	13 (15.7)
	95% CI	(12.9, 34.6)	(7.8, 23.5)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5150	
	95% CI	(0.7697, 2.9818)	
	Two-sided P-value	0.2292	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	2 (33.3)	3 (37.5)
	95% CI	(0.0, 71.1)	(4.0, 71.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8889	
	95% CI	(0.2101, 3.7611)	
	Two-sided P-value	0.8729	
	P-value of interaction	0.8964	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	193
	Week 26, N	177	193
	Number of Subjects with observed Case, N1 (%)	144 (81.4)	166 (86.0)
	Number of Subjects with NRI, N2 (%)	33 (18.6)	27 (14.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	51 (28.8)	37 (19.2)
	95% CI	(22.1, 35.5)	(13.6, 24.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5030	
	95% CI	(1.0373, 2.1778)	
	Two-sided P-value	0.0313	
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	129 (86.0)	121 (91.7)
	Number of Subjects with NRI, N2 (%)	21 (14.0)	11 (8.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	45 (30.0)	23 (17.4)
	95% CI	(22.7, 37.3)	(11.0, 23.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.7217	
	95% CI	(1.1038, 2.6857)	
	Two-sided P-value	0.0166	
Region of enrollment: Asia	Baseline, N	14	19
	Week 26, N	14	19
	Number of Subjects with observed Case, N1 (%)	13 (92.9)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	1 (7.1)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	4 (28.6)	6 (31.6)
	95% CI	(4.9, 52.2)	(10.7, 52.5)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9048	
	95% CI	(0.3134, 2.6120)	
	Two-sided P-value	0.8532	
Region of enrollment: Latin America	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	13 (76.5)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (23.5)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (35.3)	3 (15.8)
	95% CI	(12.6, 58.0)	(0.0, 32.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.2353	
	95% CI	(0.6588, 7.5843)	
	Two-sided P-value	0.1969	
	P-value of interaction	0.6651	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	213	219
	Week 26, N	213	219
	Number of Subjects with observed Case, N1 (%)	175 (82.2)	193 (88.1)
	Number of Subjects with NRI, N2 (%)	38 (17.8)	26 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	65 (30.5)	41 (18.7)
	95% CI	(24.3, 36.7)	(13.6, 23.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6300	
	95% CI	(1.1575, 2.2955)	
	Two-sided P-value	0.0052	
Baseline disease severity: Severe	Baseline, N	145	144
	Week 26, N	145	144
	Number of Subjects with observed Case, N1 (%)	124 (85.5)	127 (88.2)
	Number of Subjects with NRI, N2 (%)	21 (14.5)	17 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	41 (28.3)	28 (19.4)
	95% CI	(20.9, 35.6)	(13.0, 25.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4542	
	95% CI	(0.9540, 2.2167)	
	Two-sided P-value	0.0817	
	P-value of interaction	0.6804	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	38	51
	Week 26, N	38	51
	Number of Subjects with observed Case, N1 (%)	30 (78.9)	44 (86.3)
	Number of Subjects with NRI, N2 (%)	8 (21.1)	7 (13.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	11 (28.9)	12 (23.5)
	95% CI	(14.5, 43.4)	(11.9, 35.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2303	
	95% CI	(0.6097, 2.4826)	
	Two-sided P-value	0.5629	
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	320	312
	Week 26, N	320	312
	Number of Subjects with observed Case, N1 (%)	269 (84.1)	276 (88.5)
	Number of Subjects with NRI, N2 (%)	51 (15.9)	36 (11.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Responders, n (%)	95 (29.7)	57 (18.3)
	95% CI	(24.7, 34.7)	(14.0, 22.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6250	
	95% CI	(1.2172, 2.1695)	
	Two-sided P-value	0.0010	
	P-value of interaction	0.4725	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	130	136
	Week 26, N	130	136
	Number of Subjects with observed Case, N1 (%)	106 (81.5)	120 (88.2)
	Number of Subjects with NRI, N2 (%)	24 (18.5)	16 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	31 (23.8)	28 (20.6)
	95% CI	(16.5, 31.2)	(13.8, 27.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1582	
	95% CI	(0.7379, 1.8181)	
	Two-sided P-value	0.5231	
Weight (kg): >=70 and <=100	Baseline, N	194	183
	Week 26, N	194	183
	Number of Subjects with observed Case, N1 (%)	166 (85.6)	165 (90.2)
	Number of Subjects with NRI, N2 (%)	28 (14.4)	18 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Responders, n (%)	65 (33.5)	31 (16.9)
	95% CI	(26.9, 40.1)	(11.5, 22.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.9779	
	95% CI	(1.3565, 2.8839)	
	Two-sided P-value	0.0004	
Weight (kg): >100	Baseline, N	34	44
	Week 26, N	34	44
	Number of Subjects with observed Case, N1 (%)	27 (79.4)	35 (79.5)
	Number of Subjects with NRI, N2 (%)	7 (20.6)	9 (20.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	10 (29.4)	10 (22.7)
	95% CI	(14.1, 44.7)	(10.3, 35.1)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2941	
	95% CI	(0.6091, 2.7497)	
	Two-sided P-value	0.5025	
	P-value of interaction	0.1801	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	219	218
	Week 26, N	219	218
	Number of Subjects with observed Case, N1 (%)	182 (83.1)	192 (88.1)
	Number of Subjects with NRI, N2 (%)	37 (16.9)	26 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	65 (29.7)	43 (19.7)
	95% CI	(23.6, 35.7)	(14.4, 25.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5047	
	95% CI	(1.0747, 2.1068)	
	Two-sided P-value	0.0173	
AD Duration (years) group: >=26	Baseline, N	139	145
	Week 26, N	139	145
	Number of Subjects with observed Case, N1 (%)	117 (84.2)	128 (88.3)
	Number of Subjects with NRI, N2 (%)	22 (15.8)	17 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Responders, n (%)	41 (29.5)	26 (17.9)
	95% CI	(21.9, 37.1)	(11.7, 24.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6450	
	95% CI	(1.0671, 2.5359)	
	Two-sided P-value	0.0242	
	P-value of interaction	0.7500	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	178	182
	Week 26, N	178	182
	Number of Subjects with observed Case, N1 (%)	142 (79.8)	160 (87.9)
	Number of Subjects with NRI, N2 (%)	36 (20.2)	22 (12.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	49 (27.5)	40 (22.0)
	95% CI	(21.0, 34.1)	(16.0, 28.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2525	
	95% CI	(0.8713, 1.8006)	
	Two-sided P-value	0.2240	
Baseline EASI group: >25	Baseline, N	171	174
	Week 26, N	171	174
	Number of Subjects with observed Case, N1 (%)	150 (87.7)	154 (88.5)
	Number of Subjects with NRI, N2 (%)	21 (12.3)	20 (11.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Responders, n (%)	53 (31.0)	26 (14.9)
	95% CI	(24.1, 37.9)	(9.6, 20.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.0742	
	95% CI	(1.3640, 3.1542)	
	Two-sided P-value	0.0006	
	P-value of interaction	0.0746	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	122	131
	Week 26, N	122	131
	Number of Subjects with observed Case, N1 (%)	99 (81.1)	118 (90.1)
	Number of Subjects with NRI, N2 (%)	23 (18.9)	13 (9.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	36 (29.5)	31 (23.7)
	95% CI	(21.4, 37.6)	(16.4, 30.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2470	
	95% CI	(0.8258, 1.8829)	
	Two-sided P-value	0.2938	
Baseline % BSA group: >30-50	Baseline, N	130	121
	Week 26, N	130	121
	Number of Subjects with observed Case, N1 (%)	109 (83.8)	106 (87.6)
	Number of Subjects with NRI, N2 (%)	21 (16.2)	15 (12.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Responders, n (%)	41 (31.5)	24 (19.8)
	95% CI	(23.6, 39.5)	(12.7, 26.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5901	
	95% CI	(1.0254, 2.4657)	
	Two-sided P-value	0.0383	
Baseline % BSA group: >50	Baseline, N	106	111
	Week 26, N	106	111
	Number of Subjects with observed Case, N1 (%)	91 (85.8)	96 (86.5)
	Number of Subjects with NRI, N2 (%)	15 (14.2)	15 (13.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	29 (27.4)	14 (12.6)
	95% CI	(18.9, 35.8)	(6.4, 18.8)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.1691	
	95% CI	(1.2149, 3.8728)	
	Two-sided P-value	0.0088	
	P-value of interaction	0.3059	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	168	176
	Week 26, N	168	176
	Number of Subjects with observed Case, N1 (%)	137 (81.5)	159 (90.3)
	Number of Subjects with NRI, N2 (%)	31 (18.5)	17 (9.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	48 (28.6)	39 (22.2)
	95% CI	(21.7, 35.4)	(16.0, 28.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2894	
	95% CI	(0.8943, 1.8589)	
	Two-sided P-value	0.1733	
Prior AD medications: Topical Agents Only	Baseline, N	188	187
	Week 26, N	188	187
	Number of Subjects with observed Case, N1 (%)	160 (85.1)	161 (86.1)
	Number of Subjects with NRI, N2 (%)	28 (14.9)	26 (13.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Responders, n (%)	58 (30.9)	30 (16.0)
	95% CI	(24.2, 37.5)	(10.8, 21.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.9230	
	95% CI	(1.3000, 2.8447)	
	Two-sided P-value	0.0011	
	P-value of interaction	0.1437	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	80	104
	Week 26, N	80	104
	Number of Subjects with observed Case, N1 (%)	72 (90.0)	93 (89.4)
	Number of Subjects with NRI, N2 (%)	8 (10.0)	11 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	30 (37.5)	20 (19.2)
	95% CI	(26.9, 48.1)	(11.7, 26.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.9500	
	95% CI	(1.2007, 3.1669)	
	Two-sided P-value	0.0070	
Baseline PP-NRS group: >=7	Baseline, N	273	258
	Week 26, N	273	258
	Number of Subjects with observed Case, N1 (%)	225 (82.4)	226 (87.6)
	Number of Subjects with NRI, N2 (%)	48 (17.6)	32 (12.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Responders, n (%)	75 (27.5)	49 (19.0)
	95% CI	(22.2, 32.8)	(14.2, 23.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4465	
	95% CI	(1.0533, 1.9866)	
	Two-sided P-value	0.0226	
	P-value of interaction	0.3124	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	225	246
	Week 26, N	225	246
	Number of Subjects with observed Case, N1 (%)	181 (80.4)	217 (88.2)
	Number of Subjects with NRI, N2 (%)	44 (19.6)	29 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	158 (70.2)	200 (81.3)
	95% CI	(64.2, 76.2)	(76.4, 86.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8637	
	95% CI	(0.7784, 0.9585)	
	Two-sided P-value	0.0058	
Age (years) group: >=40	Baseline, N	131	117
	Week 26, N	131	117
	Number of Subjects with observed Case, N1 (%)	116 (88.5)	103 (88.0)
	Number of Subjects with NRI, N2 (%)	15 (11.5)	14 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	113 (86.3)	89 (76.1)
	95% CI	(80.4, 92.2)	(68.3, 83.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1340	
	95% CI	(1.0033, 1.2817)	
	Two-sided P-value	0.0442	
	P-value of interaction	0.0009	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	335	352
	Week 26, N	335	352
	Number of Subjects with observed Case, N1 (%)	280 (83.6)	310 (88.1)
	Number of Subjects with NRI, N2 (%)	55 (16.4)	42 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	255 (76.1)	280 (79.5)
	95% CI	(71.6, 80.7)	(75.3, 83.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9569	
	95% CI	(0.8833, 1.0367)	
	Two-sided P-value	0.2809	
Age (years) group: >=65	Baseline, N	21	11
	Week 26, N	21	11
	Number of Subjects with observed Case, N1 (%)	17 (81.0)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	4 (19.0)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Responders, n (%)	16 (76.2)	9 (81.8)
	95% CI	(58.0, 94.4)	(59.0, 100.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9312	
	95% CI	(0.6451, 1.3443)	
	Two-sided P-value	0.7036	
	P-value of interaction	0.8870	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	188	202
	Week 26, N	188	202
	Number of Subjects with observed Case, N1 (%)	165 (87.8)	178 (88.1)
	Number of Subjects with NRI, N2 (%)	23 (12.2)	24 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	146 (77.7)	159 (78.7)
	95% CI	(71.7, 83.6)	(73.1, 84.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9866	
	95% CI	(0.8883, 1.0958)	
	Two-sided P-value	0.8014	
Sex: Female	Baseline, N	168	161
	Week 26, N	168	161
	Number of Subjects with observed Case, N1 (%)	132 (78.6)	142 (88.2)
	Number of Subjects with NRI, N2 (%)	36 (21.4)	19 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	125 (74.4)	130 (80.7)
	95% CI	(67.8, 81.0)	(74.7, 86.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9215	
	95% CI	(0.8202, 1.0353)	
	Two-sided P-value	0.1686	
	P-value of interaction	0.3931	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	266	247
	Week 26, N	266	247
	Number of Subjects with observed Case, N1 (%)	218 (82.0)	217 (87.9)
	Number of Subjects with NRI, N2 (%)	48 (18.0)	30 (12.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	198 (74.4)	201 (81.4)
	95% CI	(69.2, 79.7)	(76.5, 86.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9147	
	95% CI	(0.8341, 1.0032)	
	Two-sided P-value	0.0584	
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	25	25
	Week 26, N	25	25
	Number of Subjects with observed Case, N1 (%)	19 (76.0)	20 (80.0)
	Number of Subjects with NRI, N2 (%)	6 (24.0)	5 (20.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Responders, n (%)	18 (72.0)	16 (64.0)
	95% CI	(54.4, 89.6)	(45.2, 82.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1250	
	95% CI	(0.7675, 1.6489)	
	Two-sided P-value	0.5460	
Race: ASIAN	Baseline, N	59	83
	Week 26, N	59	83
	Number of Subjects with observed Case, N1 (%)	54 (91.5)	75 (90.4)
	Number of Subjects with NRI, N2 (%)	5 (8.5)	8 (9.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	49 (83.1)	66 (79.5)
	95% CI	(73.5, 92.6)	(70.8, 88.2)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0444	
	95% CI	(0.8911, 1.2241)	
	Two-sided P-value	0.5915	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (100.0)	6 (75.0)
	95% CI	(54.1, 100.0)	(45.0, 100.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3333	
	95% CI	(0.8937, 1.9893)	
	Two-sided P-value	0.1587	
	P-value of interaction	0.2692	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	193
	Week 26, N	177	193
	Number of Subjects with observed Case, N1 (%)	144 (81.4)	166 (86.0)
	Number of Subjects with NRI, N2 (%)	33 (18.6)	27 (14.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	136 (76.8)	149 (77.2)
	95% CI	(70.6, 83.1)	(71.3, 83.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9953	
	95% CI	(0.8903, 1.1126)	
	Two-sided P-value	0.9334	
Region of enrollment: Europe	Baseline, N	148	132
	Week 26, N	148	132
	Number of Subjects with observed Case, N1 (%)	127 (85.8)	121 (91.7)
	Number of Subjects with NRI, N2 (%)	21 (14.2)	11 (8.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	113 (76.4)	109 (82.6)
	95% CI	(69.5, 83.2)	(76.1, 89.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9246	
	95% CI	(0.8208, 1.0416)	
	Two-sided P-value	0.1971	
Region of enrollment: Asia	Baseline, N	14	19
	Week 26, N	14	19
	Number of Subjects with observed Case, N1 (%)	13 (92.9)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	1 (7.1)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	11 (78.6)	17 (89.5)
	95% CI	(57.1, 100.0)	(75.7, 100.0)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8782	
	95% CI	(0.6415, 1.2021)	
	Two-sided P-value	0.4174	
Region of enrollment: Latin America	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	13 (76.5)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (23.5)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	11 (64.7)	14 (73.7)
	95% CI	(42.0, 87.4)	(53.9, 93.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8782	
	95% CI	(0.5644, 1.3664)	
	Two-sided P-value	0.5646	
	P-value of interaction	0.7478	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	211	219
	Week 26, N	211	219
	Number of Subjects with observed Case, N1 (%)	173 (82.0)	193 (88.1)
	Number of Subjects with NRI, N2 (%)	38 (18.0)	26 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	157 (74.4)	169 (77.2)
	95% CI	(68.5, 80.3)	(71.6, 82.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9642	
	95% CI	(0.8664, 1.0731)	
	Two-sided P-value	0.5045	
Baseline disease severity: Severe	Baseline, N	145	144
	Week 26, N	145	144
	Number of Subjects with observed Case, N1 (%)	124 (85.5)	127 (88.2)
	Number of Subjects with NRI, N2 (%)	21 (14.5)	17 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	114 (78.6)	120 (83.3)
	95% CI	(71.9, 85.3)	(77.2, 89.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9434	
	95% CI	(0.8435, 1.0552)	
	Two-sided P-value	0.3082	
	P-value of interaction	0.7829	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	38	51
	Week 26, N	38	51
	Number of Subjects with observed Case, N1 (%)	30 (78.9)	44 (86.3)
	Number of Subjects with NRI, N2 (%)	8 (21.1)	7 (13.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	26 (68.4)	38 (74.5)
	95% CI	(53.6, 83.2)	(62.5, 86.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9183	
	95% CI	(0.7016, 1.2019)	
	Two-sided P-value	0.5347	
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	318	312
	Week 26, N	318	312
	Number of Subjects with observed Case, N1 (%)	267 (84.0)	276 (88.5)
	Number of Subjects with NRI, N2 (%)	51 (16.0)	36 (11.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Responders, n (%)	245 (77.0)	251 (80.4)
	95% CI	(72.4, 81.7)	(76.0, 84.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9577	
	95% CI	(0.8830, 1.0387)	
	Two-sided P-value	0.2965	
	P-value of interaction	0.7696	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	130	136
	Week 26, N	130	136
	Number of Subjects with observed Case, N1 (%)	106 (81.5)	120 (88.2)
	Number of Subjects with NRI, N2 (%)	24 (18.5)	16 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	95 (73.1)	110 (80.9)
	95% CI	(65.5, 80.7)	(74.3, 87.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9035	
	95% CI	(0.7914, 1.0315)	
	Two-sided P-value	0.1334	
Weight (kg): >=70 and <=100	Baseline, N	192	183
	Week 26, N	192	183
	Number of Subjects with observed Case, N1 (%)	164 (85.4)	165 (90.2)
	Number of Subjects with NRI, N2 (%)	28 (14.6)	18 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Responders, n (%)	150 (78.1)	147 (80.3)
	95% CI	(72.3, 84.0)	(74.6, 86.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9726	
	95% CI	(0.8768, 1.0788)	
	Two-sided P-value	0.5990	
Weight (kg): >100	Baseline, N	34	44
	Week 26, N	34	44
	Number of Subjects with observed Case, N1 (%)	27 (79.4)	35 (79.5)
	Number of Subjects with NRI, N2 (%)	7 (20.6)	9 (20.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	26 (76.5)	32 (72.7)
	95% CI	(62.2, 90.7)	(59.6, 85.9)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0515	
	95% CI	(0.8109, 1.3634)	
	Two-sided P-value	0.7050	
	P-value of interaction	0.5173	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	217	218
	Week 26, N	217	218
	Number of Subjects with observed Case, N1 (%)	180 (82.9)	192 (88.1)
	Number of Subjects with NRI, N2 (%)	37 (17.1)	26 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	158 (72.8)	174 (79.8)
	95% CI	(66.9, 78.7)	(74.5, 85.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9122	
	95% CI	(0.8211, 1.0134)	
	Two-sided P-value	0.0870	
AD Duration (years) group: >=26	Baseline, N	139	145
	Week 26, N	139	145
	Number of Subjects with observed Case, N1 (%)	117 (84.2)	128 (88.3)
	Number of Subjects with NRI, N2 (%)	22 (15.8)	17 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Responders, n (%)	113 (81.3)	115 (79.3)
	95% CI	(74.8, 87.8)	(72.7, 85.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0250	
	95% CI	(0.9135, 1.1502)	
	Two-sided P-value	0.6741	
	P-value of interaction	0.1430	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	178	182
	Week 26, N	178	182
	Number of Subjects with observed Case, N1 (%)	142 (79.8)	160 (87.9)
	Number of Subjects with NRI, N2 (%)	36 (20.2)	22 (12.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	126 (70.8)	139 (76.4)
	95% CI	(64.1, 77.5)	(70.2, 82.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9268	
	95% CI	(0.8186, 1.0495)	
	Two-sided P-value	0.2307	
Baseline EASI group: >25	Baseline, N	169	174
	Week 26, N	169	174
	Number of Subjects with observed Case, N1 (%)	148 (87.6)	154 (88.5)
	Number of Subjects with NRI, N2 (%)	21 (12.4)	20 (11.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Responders, n (%)	138 (81.7)	144 (82.8)
	95% CI	(75.8, 87.5)	(77.1, 88.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9867	
	95% CI	(0.8941, 1.0888)	
	Two-sided P-value	0.7897	
	P-value of interaction	0.4393	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	122	131
	Week 26, N	122	131
	Number of Subjects with observed Case, N1 (%)	99 (81.1)	118 (90.1)
	Number of Subjects with NRI, N2 (%)	23 (18.9)	13 (9.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	87 (71.3)	105 (80.2)
	95% CI	(63.3, 79.3)	(73.3, 87.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8897	
	95% CI	(0.7726, 1.0246)	
	Two-sided P-value	0.1047	
Baseline % BSA group: >30-50	Baseline, N	128	121
	Week 26, N	128	121
	Number of Subjects with observed Case, N1 (%)	107 (83.6)	106 (87.6)
	Number of Subjects with NRI, N2 (%)	21 (16.4)	15 (12.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Responders, n (%)	99 (77.3)	95 (78.5)
	95% CI	(70.1, 84.6)	(71.2, 85.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9851	
	95% CI	(0.8631, 1.1244)	
	Two-sided P-value	0.8241	
Baseline % BSA group: >50	Baseline, N	106	111
	Week 26, N	106	111
	Number of Subjects with observed Case, N1 (%)	91 (85.8)	96 (86.5)
	Number of Subjects with NRI, N2 (%)	15 (14.2)	15 (13.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	85 (80.2)	89 (80.2)
	95% CI	(72.6, 87.8)	(72.8, 87.6)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0001	
	95% CI	(0.8762, 1.1416)	
	Two-sided P-value	0.9987	
	P-value of interaction	0.4428	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	167	176
	Week 26, N	167	176
	Number of Subjects with observed Case, N1 (%)	136 (81.4)	159 (90.3)
	Number of Subjects with NRI, N2 (%)	31 (18.6)	17 (9.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	125 (74.9)	145 (82.4)
	95% CI	(68.3, 81.4)	(76.8, 88.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9085	
	95% CI	(0.8128, 1.0155)	
	Two-sided P-value	0.0913	
Prior AD medications: Topical Agents Only	Baseline, N	187	187
	Week 26, N	187	187
	Number of Subjects with observed Case, N1 (%)	159 (85.0)	161 (86.1)
	Number of Subjects with NRI, N2 (%)	28 (15.0)	26 (13.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Responders, n (%)	144 (77.0)	144 (77.0)
	95% CI	(71.0, 83.0)	(71.0, 83.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0000	
	95% CI	(0.8952, 1.1171)	
	Two-sided P-value	1.0000	
	P-value of interaction	0.2312	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	79	104
	Week 26, N	79	104
	Number of Subjects with observed Case, N1 (%)	71 (89.9)	93 (89.4)
	Number of Subjects with NRI, N2 (%)	8 (10.1)	11 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	65 (82.3)	81 (77.9)
	95% CI	(73.9, 90.7)	(69.9, 85.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0564	
	95% CI	(0.9140, 1.2210)	
	Two-sided P-value	0.4575	
Baseline PP-NRS group: >=7	Baseline, N	272	258
	Week 26, N	272	258
	Number of Subjects with observed Case, N1 (%)	224 (82.4)	226 (87.6)
	Number of Subjects with NRI, N2 (%)	48 (17.6)	32 (12.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score >= 5 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 5, NRI) (Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Responders, n (%)	204 (75.0)	207 (80.2)
	95% CI	(69.9, 80.1)	(75.4, 85.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9348	
	95% CI	(0.8530, 1.0244)	
	Two-sided P-value	0.1487	
	P-value of interaction	0.1616	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	230	246
	Week 26, N	230	246
	Number of Subjects with observed Case, N1 (%)	184 (80.0)	217 (88.2)
	Number of Subjects with NRI, N2 (%)	46 (20.0)	29 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	82 (35.7)	83 (33.7)
	95% CI	(29.5, 41.8)	(27.8, 39.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0567	
	95% CI	(0.8257, 1.3522)	
	Two-sided P-value	0.6613	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Baseline, N	132	117
	Week 26, N	132	117
	Number of Subjects with observed Case, N1 (%)	117 (88.6)	103 (88.0)
	Number of Subjects with NRI, N2 (%)	15 (11.4)	14 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	49 (37.1)	34 (29.1)
	95% CI	(28.9, 45.4)	(20.8, 37.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2774	
	95% CI	(0.8914, 1.8306)	
	Two-sided P-value	0.1823	
	P-value of interaction	0.3940	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	341	352
	Week 26, N	341	352
	Number of Subjects with observed Case, N1 (%)	284 (83.3)	310 (88.1)
	Number of Subjects with NRI, N2 (%)	57 (16.7)	42 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	123 (36.1)	115 (32.7)
	95% CI	(31.0, 41.2)	(27.8, 37.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1041	
	95% CI	(0.8985, 1.3567)	
	Two-sided P-value	0.3463	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Baseline, N	21	11
	Week 26, N	21	11
	Number of Subjects with observed Case, N1 (%)	17 (81.0)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	4 (19.0)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	8 (38.1)	2 (18.2)
	95% CI	(17.3, 58.9)	(0.0, 41.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.0952	
	95% CI	(0.5340, 8.2210)	
	Two-sided P-value	0.2889	
	P-value of interaction	0.3637	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	193	202
	Week 26, N	193	202
	Number of Subjects with observed Case, N1 (%)	169 (87.6)	178 (88.1)
	Number of Subjects with NRI, N2 (%)	24 (12.4)	24 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	69 (35.8)	59 (29.2)
	95% CI	(29.0, 42.5)	(22.9, 35.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2240	
	95% CI	(0.9195, 1.6295)	
	Two-sided P-value	0.1661	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Baseline, N	169	161
	Week 26, N	169	161
	Number of Subjects with observed Case, N1 (%)	132 (78.1)	142 (88.2)
	Number of Subjects with NRI, N2 (%)	37 (21.9)	19 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	62 (36.7)	58 (36.0)
	95% CI	(29.4, 44.0)	(28.6, 43.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0184	
	95% CI	(0.7653, 1.3551)	
	Two-sided P-value	0.9006	
	P-value of interaction	0.3725	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	269	247
	Week 26, N	269	247
	Number of Subjects with observed Case, N1 (%)	219 (81.4)	217 (87.9)
	Number of Subjects with NRI, N2 (%)	50 (18.6)	30 (12.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	92 (34.2)	82 (33.2)
	95% CI	(28.5, 39.9)	(27.3, 39.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0302	
	95% CI	(0.8084, 1.3128)	
	Two-sided P-value	0.8099	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	25	26
	Week 26, N	25	26
	Number of Subjects with observed Case, N1 (%)	19 (76.0)	21 (80.8)
	Number of Subjects with NRI, N2 (%)	6 (24.0)	5 (19.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	9 (36.0)	7 (26.9)
	95% CI	(17.2, 54.8)	(9.9, 44.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3371	
	95% CI	(0.5883, 3.0393)	
	Two-sided P-value	0.4880	
Race: ASIAN	Baseline, N	62	82
	Week 26, N	62	82
	Number of Subjects with observed Case, N1 (%)	57 (91.9)	74 (90.2)
	Number of Subjects with NRI, N2 (%)	5 (8.1)	8 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: ASIAN	Responders, n (%)	26 (41.9)	26 (31.7)
	95% CI	(29.7, 54.2)	(21.6, 41.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3226	
	95% CI	(0.8586, 2.0374)	
	Two-sided P-value	0.2047	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	4 (66.7)	2 (25.0)
	95% CI	(28.9, 100.0)	(0.0, 55.0)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.6667	
	95% CI	(0.7075, 10.0516)	
	Two-sided P-value	0.1474	
	P-value of interaction	0.4172	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	193
	Week 26, N	177	193
	Number of Subjects with observed Case, N1 (%)	142 (80.2)	166 (86.0)
	Number of Subjects with NRI, N2 (%)	35 (19.8)	27 (14.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	61 (34.5)	63 (32.6)
	95% CI	(27.5, 41.5)	(26.0, 39.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0558	
	95% CI	(0.7924, 1.4067)	
	Two-sided P-value	0.7108	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	129 (86.0)	121 (91.7)
	Number of Subjects with NRI, N2 (%)	21 (14.0)	11 (8.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	57 (38.0)	47 (35.6)
	95% CI	(30.2, 45.8)	(27.4, 43.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0672	
	95% CI	(0.7849, 1.4511)	
	Two-sided P-value	0.6781	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	16 (94.1)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	1 (5.9)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Asia	Responders, n (%)	6 (35.3)	5 (26.3)
	95% CI	(12.6, 58.0)	(6.5, 46.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3412	
	95% CI	(0.4983, 3.6099)	
	Two-sided P-value	0.5612	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	7 (38.9)	2 (10.5)
	95% CI	(16.4, 61.4)	(0.0, 24.3)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	3.6944	
	95% CI	(0.8813, 15.4866)	
	Two-sided P-value	0.0739	
	P-value of interaction	0.3894	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	216	218
	Week 26, N	216	218
	Number of Subjects with observed Case, N1 (%)	176 (81.5)	192 (88.1)
	Number of Subjects with NRI, N2 (%)	40 (18.5)	26 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	70 (32.4)	54 (24.8)
	95% CI	(26.2, 38.6)	(19.0, 30.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3083	
	95% CI	(0.9682, 1.7678)	
	Two-sided P-value	0.0802	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Baseline, N	146	145
	Week 26, N	146	145
	Number of Subjects with observed Case, N1 (%)	125 (85.6)	128 (88.3)
	Number of Subjects with NRI, N2 (%)	21 (14.4)	17 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	61 (41.8)	63 (43.4)
	95% CI	(33.8, 49.8)	(35.4, 51.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9616	
	95% CI	(0.7365, 1.2556)	
	Two-sided P-value	0.7737	
	P-value of interaction	0.1335	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	40	50
	Week 26, N	40	50
	Number of Subjects with observed Case, N1 (%)	32 (80.0)	43 (86.0)
	Number of Subjects with NRI, N2 (%)	8 (20.0)	7 (14.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	16 (40.0)	15 (30.0)
	95% CI	(24.8, 55.2)	(17.3, 42.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3333	
	95% CI	(0.7551, 2.3544)	
	Two-sided P-value	0.3214	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	322	313
	Week 26, N	322	313
	Number of Subjects with observed Case, N1 (%)	269 (83.5)	277 (88.5)
	Number of Subjects with NRI, N2 (%)	53 (16.5)	36 (11.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	115 (35.7)	102 (32.6)
	95% CI	(30.5, 40.9)	(27.4, 37.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0959	
	95% CI	(0.8826, 1.3608)	
	Two-sided P-value	0.4069	
	P-value of interaction	0.5276	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	132	136
	Week 26, N	132	136
	Number of Subjects with observed Case, N1 (%)	107 (81.1)	120 (88.2)
	Number of Subjects with NRI, N2 (%)	25 (18.9)	16 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	45 (34.1)	52 (38.2)
	95% CI	(26.0, 42.2)	(30.1, 46.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8916	
	95% CI	(0.6480, 1.2269)	
	Two-sided P-value	0.4812	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Baseline, N	196	182
	Week 26, N	196	182
	Number of Subjects with observed Case, N1 (%)	167 (85.2)	164 (90.1)
	Number of Subjects with NRI, N2 (%)	29 (14.8)	18 (9.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	75 (38.3)	52 (28.6)
	95% CI	(31.5, 45.1)	(22.0, 35.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3393	
	95% CI	(1.0016, 1.7907)	
	Two-sided P-value	0.0487	
Weight (kg): >100	Baseline, N	34	45
	Week 26, N	34	45
	Number of Subjects with observed Case, N1 (%)	27 (79.4)	36 (80.0)
	Number of Subjects with NRI, N2 (%)	7 (20.6)	9 (20.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >100	Responders, n (%)	11 (32.4)	13 (28.9)
	95% CI	(16.6, 48.1)	(15.6, 42.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1199	
	95% CI	(0.5742, 2.1844)	
	Two-sided P-value	0.7397	
	P-value of interaction	0.1814	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	222	218
	Week 26, N	222	218
	Number of Subjects with observed Case, N1 (%)	185 (83.3)	192 (88.1)
	Number of Subjects with NRI, N2 (%)	37 (16.7)	26 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	76 (34.2)	63 (28.9)
	95% CI	(28.0, 40.5)	(22.9, 34.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1846	
	95% CI	(0.8982, 1.5623)	
	Two-sided P-value	0.2302	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Baseline, N	140	145
	Week 26, N	140	145
	Number of Subjects with observed Case, N1 (%)	116 (82.9)	128 (88.3)
	Number of Subjects with NRI, N2 (%)	24 (17.1)	17 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	55 (39.3)	54 (37.2)
	95% CI	(31.2, 47.4)	(29.4, 45.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0549	
	95% CI	(0.7854, 1.4169)	
	Two-sided P-value	0.7226	
	P-value of interaction	0.5742	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	181	182
	Week 26, N	181	182
	Number of Subjects with observed Case, N1 (%)	144 (79.6)	160 (87.9)
	Number of Subjects with NRI, N2 (%)	37 (20.4)	22 (12.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	51 (28.2)	52 (28.6)
	95% CI	(21.6, 34.7)	(22.0, 35.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9862	
	95% CI	(0.7112, 1.3675)	
	Two-sided P-value	0.9335	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Baseline, N	172	173
	Week 26, N	172	173
	Number of Subjects with observed Case, N1 (%)	151 (87.8)	153 (88.4)
	Number of Subjects with NRI, N2 (%)	21 (12.2)	20 (11.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	78 (45.3)	64 (37.0)
	95% CI	(37.9, 52.8)	(29.8, 44.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2258	
	95% CI	(0.9505, 1.5810)	
	Two-sided P-value	0.1167	
	P-value of interaction	0.3034	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	122	132
	Week 26, N	122	132
	Number of Subjects with observed Case, N1 (%)	97 (79.5)	119 (90.2)
	Number of Subjects with NRI, N2 (%)	25 (20.5)	13 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	33 (27.0)	32 (24.2)
	95% CI	(19.2, 34.9)	(16.9, 31.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1158	
	95% CI	(0.7336, 1.6971)	
	Two-sided P-value	0.6086	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Baseline, N	132	121
	Week 26, N	132	121
	Number of Subjects with observed Case, N1 (%)	111 (84.1)	106 (87.6)
	Number of Subjects with NRI, N2 (%)	21 (15.9)	15 (12.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	57 (43.2)	39 (32.2)
	95% CI	(34.7, 51.6)	(23.9, 40.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3397	
	95% CI	(0.9689, 1.8526)	
	Two-sided P-value	0.0769	
Baseline % BSA group: >50	Baseline, N	108	110
	Week 26, N	108	110
	Number of Subjects with observed Case, N1 (%)	93 (86.1)	95 (86.4)
	Number of Subjects with NRI, N2 (%)	15 (13.9)	15 (13.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >50	Responders, n (%)	41 (38.0)	46 (41.8)
	95% CI	(28.8, 47.1)	(32.6, 51.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9078	
	95% CI	(0.6548, 1.2585)	
	Two-sided P-value	0.5617	
	P-value of interaction	0.2529	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	172	174
	Week 26, N	172	174
	Number of Subjects with observed Case, N1 (%)	140 (81.4)	157 (90.2)
	Number of Subjects with NRI, N2 (%)	32 (18.6)	17 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	65 (37.8)	64 (36.8)
	95% CI	(30.5, 45.0)	(29.6, 43.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0274	
	95% CI	(0.7817, 1.3504)	
	Two-sided P-value	0.8461	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Baseline, N	188	189
	Week 26, N	188	189
	Number of Subjects with observed Case, N1 (%)	159 (84.6)	163 (86.2)
	Number of Subjects with NRI, N2 (%)	29 (15.4)	26 (13.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	65 (34.6)	53 (28.0)
	95% CI	(27.8, 41.4)	(21.6, 34.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2329	
	95% CI	(0.9121, 1.6666)	
	Two-sided P-value	0.1732	
	P-value of interaction	0.3797	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	83	104
	Week 26, N	83	104
	Number of Subjects with observed Case, N1 (%)	74 (89.2)	93 (89.4)
	Number of Subjects with NRI, N2 (%)	9 (10.8)	11 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	17 (20.5)	20 (19.2)
	95% CI	(11.8, 29.2)	(11.7, 26.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0651	
	95% CI	(0.5971, 1.8996)	
	Two-sided P-value	0.8309	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index I Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Baseline, N	274	258
	Week 26, N	274	258
	Number of Subjects with observed Case, N1 (%)	225 (82.1)	226 (87.6)
	Number of Subjects with NRI, N2 (%)	49 (17.9)	32 (12.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	114 (41.6)	97 (37.6)
	95% CI	(35.8, 47.4)	(31.7, 43.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1066	
	95% CI	(0.8964, 1.3662)	
	Two-sided P-value	0.3459	
	P-value of interaction	0.9030	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	230	246
	Week 26, N	230	246
	Number of Subjects with observed Case, N1 (%)	184 (80.0)	217 (88.2)
	Number of Subjects with NRI, N2 (%)	46 (20.0)	29 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	85 (37.0)	95 (38.6)
	95% CI	(30.7, 43.2)	(32.5, 44.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9570	
	95% CI	(0.7597, 1.2055)	
	Two-sided P-value	0.7089	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Baseline, N	132	118
	Week 26, N	132	118
	Number of Subjects with observed Case, N1 (%)	117 (88.6)	104 (88.1)
	Number of Subjects with NRI, N2 (%)	15 (11.4)	14 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	54 (40.9)	45 (38.1)
	95% CI	(32.5, 49.3)	(29.4, 46.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0727	
	95% CI	(0.7884, 1.4596)	
	Two-sided P-value	0.6550	
	P-value of interaction	0.5610	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	341	353
	Week 26, N	341	353
	Number of Subjects with observed Case, N1 (%)	284 (83.3)	311 (88.1)
	Number of Subjects with NRI, N2 (%)	57 (16.7)	42 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	131 (38.4)	137 (38.8)
	95% CI	(33.3, 43.6)	(33.7, 43.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9899	
	95% CI	(0.8205, 1.1942)	
	Two-sided P-value	0.9152	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Baseline, N	21	11
	Week 26, N	21	11
	Number of Subjects with observed Case, N1 (%)	17 (81.0)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	4 (19.0)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	8 (38.1)	3 (27.3)
	95% CI	(17.3, 58.9)	(1.0, 53.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3968	
	95% CI	(0.4611, 4.2316)	
	Two-sided P-value	0.5545	
	P-value of interaction	0.5482	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	193	203
	Week 26, N	193	203
	Number of Subjects with observed Case, N1 (%)	169 (87.6)	179 (88.2)
	Number of Subjects with NRI, N2 (%)	24 (12.4)	24 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	78 (40.4)	76 (37.4)
	95% CI	(33.5, 47.3)	(30.8, 44.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0795	
	95% CI	(0.8433, 1.3818)	
	Two-sided P-value	0.5437	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Baseline, N	169	161
	Week 26, N	169	161
	Number of Subjects with observed Case, N1 (%)	132 (78.1)	142 (88.2)
	Number of Subjects with NRI, N2 (%)	37 (21.9)	19 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	61 (36.1)	64 (39.8)
	95% CI	(28.9, 43.3)	(32.2, 47.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9080	
	95% CI	(0.6887, 1.1971)	
	Two-sided P-value	0.4938	
	P-value of interaction	0.3603	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	269	247
	Week 26, N	269	247
	Number of Subjects with observed Case, N1 (%)	219 (81.4)	217 (87.9)
	Number of Subjects with NRI, N2 (%)	50 (18.6)	30 (12.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	102 (37.9)	102 (41.3)
	95% CI	(32.1, 43.7)	(35.2, 47.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9182	
	95% CI	(0.7419, 1.1365)	
	Two-sided P-value	0.4330	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	25	26
	Week 26, N	25	26
	Number of Subjects with observed Case, N1 (%)	19 (76.0)	21 (80.8)
	Number of Subjects with NRI, N2 (%)	6 (24.0)	5 (19.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	7 (28.0)	7 (26.9)
	95% CI	(10.4, 45.6)	(9.9, 44.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0400	
	95% CI	(0.4261, 2.5383)	
	Two-sided P-value	0.9313	
Race: ASIAN	Baseline, N	62	83
	Week 26, N	62	83
	Number of Subjects with observed Case, N1 (%)	57 (91.9)	75 (90.4)
	Number of Subjects with NRI, N2 (%)	5 (8.1)	8 (9.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: ASIAN	Responders, n (%)	26 (41.9)	29 (34.9)
	95% CI	(29.7, 54.2)	(24.7, 45.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2002	
	95% CI	(0.7928, 1.8170)	
	Two-sided P-value	0.3884	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	4 (66.7)	2 (25.0)
	95% CI	(28.9, 100.0)	(0.0, 55.0)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.6667	
	95% CI	(0.7075, 10.0516)	
	Two-sided P-value	0.1474	
	P-value of interaction	0.3260	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	194
	Week 26, N	177	194
	Number of Subjects with observed Case, N1 (%)	142 (80.2)	167 (86.1)
	Number of Subjects with NRI, N2 (%)	35 (19.8)	27 (13.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	69 (39.0)	72 (37.1)
	95% CI	(31.8, 46.2)	(30.3, 43.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0504	
	95% CI	(0.8100, 1.3621)	
	Two-sided P-value	0.7109	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	129 (86.0)	121 (91.7)
	Number of Subjects with NRI, N2 (%)	21 (14.0)	11 (8.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	58 (38.7)	58 (43.9)
	95% CI	(30.9, 46.5)	(35.5, 52.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8800	
	95% CI	(0.6659, 1.1630)	
	Two-sided P-value	0.3689	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	16 (94.1)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	1 (5.9)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Asia	Responders, n (%)	5 (29.4)	5 (26.3)
	95% CI	(7.8, 51.1)	(6.5, 46.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1176	
	95% CI	(0.3900, 3.2029)	
	Two-sided P-value	0.8360	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	7 (38.9)	5 (26.3)
	95% CI	(16.4, 61.4)	(6.5, 46.1)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4778	
	95% CI	(0.5718, 3.8190)	
	Two-sided P-value	0.4201	
	P-value of interaction	0.6552	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	216	219
	Week 26, N	216	219
	Number of Subjects with observed Case, N1 (%)	176 (81.5)	193 (88.1)
	Number of Subjects with NRI, N2 (%)	40 (18.5)	26 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	74 (34.3)	72 (32.9)
	95% CI	(27.9, 40.6)	(26.7, 39.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0421	
	95% CI	(0.7999, 1.3575)	
	Two-sided P-value	0.7602	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Baseline, N	146	145
	Week 26, N	146	145
	Number of Subjects with observed Case, N1 (%)	125 (85.6)	128 (88.3)
	Number of Subjects with NRI, N2 (%)	21 (14.4)	17 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	65 (44.5)	68 (46.9)
	95% CI	(36.5, 52.6)	(38.8, 55.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9493	
	95% CI	(0.7389, 1.2197)	
	Two-sided P-value	0.6842	
	P-value of interaction	0.6161	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	40	50
	Week 26, N	40	50
	Number of Subjects with observed Case, N1 (%)	32 (80.0)	43 (86.0)
	Number of Subjects with NRI, N2 (%)	8 (20.0)	7 (14.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	17 (42.5)	17 (34.0)
	95% CI	(27.2, 57.8)	(20.9, 47.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2500	
	95% CI	(0.7370, 2.1200)	
	Two-sided P-value	0.4077	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	322	314
	Week 26, N	322	314
	Number of Subjects with observed Case, N1 (%)	269 (83.5)	278 (88.5)
	Number of Subjects with NRI, N2 (%)	53 (16.5)	36 (11.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	122 (37.9)	123 (39.2)
	95% CI	(32.6, 43.2)	(33.8, 44.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9672	
	95% CI	(0.7948, 1.1771)	
	Two-sided P-value	0.7394	
	P-value of interaction	0.3725	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	132	136
	Week 26, N	132	136
	Number of Subjects with observed Case, N1 (%)	107 (81.1)	120 (88.2)
	Number of Subjects with NRI, N2 (%)	25 (18.9)	16 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	43 (32.6)	58 (42.6)
	95% CI	(24.6, 40.6)	(34.3, 51.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.7638	
	95% CI	(0.5583, 1.0450)	
	Two-sided P-value	0.0920	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Baseline, N	196	183
	Week 26, N	196	183
	Number of Subjects with observed Case, N1 (%)	167 (85.2)	165 (90.2)
	Number of Subjects with NRI, N2 (%)	29 (14.8)	18 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	85 (43.4)	69 (37.7)
	95% CI	(36.4, 50.3)	(30.7, 44.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1502	
	95% CI	(0.8998, 1.4702)	
	Two-sided P-value	0.2640	
Weight (kg): >100	Baseline, N	34	45
	Week 26, N	34	45
	Number of Subjects with observed Case, N1 (%)	27 (79.4)	36 (80.0)
	Number of Subjects with NRI, N2 (%)	7 (20.6)	9 (20.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >100	Responders, n (%)	11 (32.4)	13 (28.9)
	95% CI	(16.6, 48.1)	(15.6, 42.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1199	
	95% CI	(0.5742, 2.1844)	
	Two-sided P-value	0.7397	
	P-value of interaction	0.1229	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	222	219
	Week 26, N	222	219
	Number of Subjects with observed Case, N1 (%)	185 (83.3)	193 (88.1)
	Number of Subjects with NRI, N2 (%)	37 (16.7)	26 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	79 (35.6)	77 (35.2)
	95% CI	(29.3, 41.9)	(28.8, 41.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0121	
	95% CI	(0.7864, 1.3026)	
	Two-sided P-value	0.9255	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Baseline, N	140	145
	Week 26, N	140	145
	Number of Subjects with observed Case, N1 (%)	116 (82.9)	128 (88.3)
	Number of Subjects with NRI, N2 (%)	24 (17.1)	17 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	60 (42.9)	63 (43.4)
	95% CI	(34.7, 51.1)	(35.4, 51.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9864	
	95% CI	(0.7556, 1.2877)	
	Two-sided P-value	0.9198	
	P-value of interaction	0.8907	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	181	183
	Week 26, N	181	183
	Number of Subjects with observed Case, N1 (%)	144 (79.6)	161 (88.0)
	Number of Subjects with NRI, N2 (%)	37 (20.4)	22 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	54 (29.8)	66 (36.1)
	95% CI	(23.2, 36.5)	(29.1, 43.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8272	
	95% CI	(0.6158, 1.1113)	
	Two-sided P-value	0.2079	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Baseline, N	172	173
	Week 26, N	172	173
	Number of Subjects with observed Case, N1 (%)	151 (87.8)	153 (88.4)
	Number of Subjects with NRI, N2 (%)	21 (12.2)	20 (11.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	84 (48.8)	72 (41.6)
	95% CI	(41.4, 56.3)	(34.3, 49.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1734	
	95% CI	(0.9290, 1.4822)	
	Two-sided P-value	0.1795	
	P-value of interaction	0.0687	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	122	133
	Week 26, N	122	133
	Number of Subjects with observed Case, N1 (%)	97 (79.5)	120 (90.2)
	Number of Subjects with NRI, N2 (%)	25 (20.5)	13 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	35 (28.7)	42 (31.6)
	95% CI	(20.7, 36.7)	(23.7, 39.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9085	
	95% CI	(0.6242, 1.3222)	
	Two-sided P-value	0.6161	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Baseline, N	132	121
	Week 26, N	132	121
	Number of Subjects with observed Case, N1 (%)	111 (84.1)	106 (87.6)
	Number of Subjects with NRI, N2 (%)	21 (15.9)	15 (12.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	61 (46.2)	47 (38.8)
	95% CI	(37.7, 54.7)	(30.2, 47.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1897	
	95% CI	(0.8906, 1.5893)	
	Two-sided P-value	0.2397	
Baseline % BSA group: >50	Baseline, N	108	110
	Week 26, N	108	110
	Number of Subjects with observed Case, N1 (%)	93 (86.1)	95 (86.4)
	Number of Subjects with NRI, N2 (%)	15 (13.9)	15 (13.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >50	Responders, n (%)	43 (39.8)	51 (46.4)
	95% CI	(30.6, 49.0)	(37.0, 55.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8588	
	95% CI	(0.6318, 1.1672)	
	Two-sided P-value	0.3308	
	P-value of interaction	0.2762	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	172	175
	Week 26, N	172	175
	Number of Subjects with observed Case, N1 (%)	140 (81.4)	158 (90.3)
	Number of Subjects with NRI, N2 (%)	32 (18.6)	17 (9.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	68 (39.5)	72 (41.1)
	95% CI	(32.2, 46.8)	(33.9, 48.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9609	
	95% CI	(0.7439, 1.2413)	
	Two-sided P-value	0.7602	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Baseline, N	188	189
	Week 26, N	188	189
	Number of Subjects with observed Case, N1 (%)	159 (84.6)	163 (86.2)
	Number of Subjects with NRI, N2 (%)	29 (15.4)	26 (13.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	70 (37.2)	68 (36.0)
	95% CI	(30.3, 44.1)	(29.1, 42.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0349	
	95% CI	(0.7934, 1.3499)	
	Two-sided P-value	0.8003	
	P-value of interaction	0.6937	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	83	105
	Week 26, N	83	105
	Number of Subjects with observed Case, N1 (%)	74 (89.2)	94 (89.5)
	Number of Subjects with NRI, N2 (%)	9 (10.8)	11 (10.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	20 (24.1)	28 (26.7)
	95% CI	(14.9, 33.3)	(18.2, 35.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9036	
	95% CI	(0.5501, 1.4844)	
	Two-sided P-value	0.6890	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Sleep Problems Index II Score >= 15 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 15, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Baseline, N	274	258
	Week 26, N	274	258
	Number of Subjects with observed Case, N1 (%)	225 (82.1)	226 (87.6)
	Number of Subjects with NRI, N2 (%)	49 (17.9)	32 (12.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	119 (43.4)	112 (43.4)
	95% CI	(37.6, 49.3)	(37.4, 49.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0005	
	95% CI	(0.8240, 1.2148)	
	Two-sided P-value	0.9963	
	P-value of interaction	0.7081	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; MOS = medical outcomes study; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	204	212
	Week 26, N	204	212
	Number of Subjects with observed Case, N1 (%)	163 (79.9)	184 (86.8)
	Number of Subjects with NRI, N2 (%)	41 (20.1)	28 (13.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	118 (57.8)	133 (62.7)
	95% CI	(51.1, 64.6)	(56.2, 69.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9220	
	95% CI	(0.7885, 1.0782)	
	Two-sided P-value	0.3091	
Age (years) group: >=40	Baseline, N	112	113
	Week 26, N	112	113
	Number of Subjects with observed Case, N1 (%)	100 (89.3)	100 (88.5)
	Number of Subjects with NRI, N2 (%)	12 (10.7)	13 (11.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	87 (77.7)	69 (61.1)
	95% CI	(70.0, 85.4)	(52.1, 70.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2721	
	95% CI	(1.0651, 1.5193)	
	Two-sided P-value	0.0079	
	P-value of interaction	0.0077	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	298	314
	Week 26, N	298	314
	Number of Subjects with observed Case, N1 (%)	247 (82.9)	274 (87.3)
	Number of Subjects with NRI, N2 (%)	51 (17.1)	40 (12.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	190 (63.8)	194 (61.8)
	95% CI	(58.3, 69.2)	(56.4, 67.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0320	
	95% CI	(0.9134, 1.1659)	
	Two-sided P-value	0.6133	
Age (years) group: >=65	Baseline, N	18	11
	Week 26, N	18	11
	Number of Subjects with observed Case, N1 (%)	16 (88.9)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	2 (11.1)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Responders, n (%)	15 (83.3)	8 (72.7)
	95% CI	(66.1, 100.0)	(46.4, 99.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1458	
	95% CI	(0.7554, 1.7382)	
	Two-sided P-value	0.5220	
	P-value of interaction	0.6366	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	163	178
	Week 26, N	163	178
	Number of Subjects with observed Case, N1 (%)	144 (88.3)	156 (87.6)
	Number of Subjects with NRI, N2 (%)	19 (11.7)	22 (12.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	98 (60.1)	107 (60.1)
	95% CI	(52.6, 67.6)	(52.9, 67.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0002	
	95% CI	(0.8412, 1.1891)	
	Two-sided P-value	0.9984	
Sex: Female	Baseline, N	153	147
	Week 26, N	153	147
	Number of Subjects with observed Case, N1 (%)	119 (77.8)	128 (87.1)
	Number of Subjects with NRI, N2 (%)	34 (22.2)	19 (12.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	107 (69.9)	95 (64.6)
	95% CI	(62.7, 77.2)	(56.9, 72.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0821	
	95% CI	(0.9236, 1.2679)	
	Two-sided P-value	0.3287	
	P-value of interaction	0.5105	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	233	229
	Week 26, N	233	229
	Number of Subjects with observed Case, N1 (%)	190 (81.5)	200 (87.3)
	Number of Subjects with NRI, N2 (%)	43 (18.5)	29 (12.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	154 (66.1)	140 (61.1)
	95% CI	(60.0, 72.2)	(54.8, 67.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0811	
	95% CI	(0.9415, 1.2414)	
	Two-sided P-value	0.2690	
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	21	23
	Week 26, N	21	23
	Number of Subjects with observed Case, N1 (%)	16 (76.2)	18 (78.3)
	Number of Subjects with NRI, N2 (%)	5 (23.8)	5 (21.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Responders, n (%)	12 (57.1)	14 (60.9)
	95% CI	(36.0, 78.3)	(40.9, 80.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9388	
	95% CI	(0.5725, 1.5393)	
	Two-sided P-value	0.8023	
Race: ASIAN	Baseline, N	56	67
	Week 26, N	56	67
	Number of Subjects with observed Case, N1 (%)	51 (91.1)	60 (89.6)
	Number of Subjects with NRI, N2 (%)	5 (8.9)	7 (10.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	34 (60.7)	43 (64.2)
	95% CI	(47.9, 73.5)	(52.7, 75.7)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9460	
	95% CI	(0.7176, 1.2472)	
	Two-sided P-value	0.6939	
Race: OTHER	Baseline, N	6	6
	Week 26, N	6	6
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	6 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	5 (83.3)	5 (83.3)
	95% CI	(53.5, 100.0)	(53.5, 100.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0000	
	95% CI	(0.6029, 1.6587)	
	Two-sided P-value	1.0000	
	P-value of interaction	0.8161	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	158	165
	Week 26, N	158	165
	Number of Subjects with observed Case, N1 (%)	129 (81.6)	140 (84.8)
	Number of Subjects with NRI, N2 (%)	29 (18.4)	25 (15.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	105 (66.5)	107 (64.8)
	95% CI	(59.1, 73.8)	(57.6, 72.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0248	
	95% CI	(0.8752, 1.1999)	
	Two-sided P-value	0.7610	
Region of enrollment: Europe	Baseline, N	129	125
	Week 26, N	129	125
	Number of Subjects with observed Case, N1 (%)	109 (84.5)	114 (91.2)
	Number of Subjects with NRI, N2 (%)	20 (15.5)	11 (8.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	83 (64.3)	74 (59.2)
	95% CI	(56.1, 72.6)	(50.6, 67.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0868	
	95% CI	(0.8951, 1.3197)	
	Two-sided P-value	0.4005	
Region of enrollment: Asia	Baseline, N	15	16
	Week 26, N	15	16
	Number of Subjects with observed Case, N1 (%)	14 (93.3)	15 (93.8)
	Number of Subjects with NRI, N2 (%)	1 (6.7)	1 (6.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (40.0)	11 (68.8)
	95% CI	(15.2, 64.8)	(46.0, 91.5)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.5818	
	95% CI	(0.2882, 1.1744)	
	Two-sided P-value	0.1307	
Region of enrollment: Latin America	Baseline, N	14	19
	Week 26, N	14	19
	Number of Subjects with observed Case, N1 (%)	11 (78.6)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	3 (21.4)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	11 (78.6)	10 (52.6)
	95% CI	(57.1, 100.0)	(30.2, 75.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4929	
	95% CI	(0.8994, 2.4780)	
	Two-sided P-value	0.1212	
	P-value of interaction	0.1887	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	186	191
	Week 26, N	186	191
	Number of Subjects with observed Case, N1 (%)	152 (81.7)	166 (86.9)
	Number of Subjects with NRI, N2 (%)	34 (18.3)	25 (13.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	121 (65.1)	117 (61.3)
	95% CI	(58.2, 71.9)	(54.3, 68.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0620	
	95% CI	(0.9101, 1.2392)	
	Two-sided P-value	0.4450	
Baseline disease severity: Severe	Baseline, N	130	134
	Week 26, N	130	134
	Number of Subjects with observed Case, N1 (%)	111 (85.4)	118 (88.1)
	Number of Subjects with NRI, N2 (%)	19 (14.6)	16 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	84 (64.6)	85 (63.4)
	95% CI	(56.4, 72.8)	(55.3, 71.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0186	
	95% CI	(0.8501, 1.2206)	
	Two-sided P-value	0.8413	
	P-value of interaction	0.7312	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	38	45
	Week 26, N	38	45
	Number of Subjects with observed Case, N1 (%)	31 (81.6)	38 (84.4)
	Number of Subjects with NRI, N2 (%)	7 (18.4)	7 (15.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	22 (57.9)	26 (57.8)
	95% CI	(42.2, 73.6)	(43.3, 72.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0020	
	95% CI	(0.6931, 1.4487)	
	Two-sided P-value	0.9914	
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	278	280
	Week 26, N	278	280
	Number of Subjects with observed Case, N1 (%)	232 (83.5)	246 (87.9)
	Number of Subjects with NRI, N2 (%)	46 (16.5)	34 (12.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Responders, n (%)	183 (65.8)	176 (62.9)
	95% CI	(60.3, 71.4)	(57.2, 68.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0473	
	95% CI	(0.9255, 1.1850)	
	Two-sided P-value	0.4641	
	P-value of interaction	0.8239	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	116	119
	Week 26, N	116	119
	Number of Subjects with observed Case, N1 (%)	93 (80.2)	103 (86.6)
	Number of Subjects with NRI, N2 (%)	23 (19.8)	16 (13.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	73 (62.9)	79 (66.4)
	95% CI	(54.1, 71.7)	(57.9, 74.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9479	
	95% CI	(0.7844, 1.1456)	
	Two-sided P-value	0.5800	
Weight (kg): >=70 and <=100	Baseline, N	172	167
	Week 26, N	172	167
	Number of Subjects with observed Case, N1 (%)	147 (85.5)	150 (89.8)
	Number of Subjects with NRI, N2 (%)	25 (14.5)	17 (10.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Responders, n (%)	113 (65.7)	100 (59.9)
	95% CI	(58.6, 72.8)	(52.4, 67.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0972	
	95% CI	(0.9307, 1.2934)	
	Two-sided P-value	0.2694	
Weight (kg): >100	Baseline, N	28	39
	Week 26, N	28	39
	Number of Subjects with observed Case, N1 (%)	23 (82.1)	31 (79.5)
	Number of Subjects with NRI, N2 (%)	5 (17.9)	8 (20.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	19 (67.9)	23 (59.0)
	95% CI	(50.6, 85.2)	(43.5, 74.4)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1506	
	95% CI	(0.7984, 1.6581)	
	Two-sided P-value	0.4517	
	P-value of interaction	0.4450	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	191	192
	Week 26, N	191	192
	Number of Subjects with observed Case, N1 (%)	161 (84.3)	167 (87.0)
	Number of Subjects with NRI, N2 (%)	30 (15.7)	25 (13.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	123 (64.4)	123 (64.1)
	95% CI	(57.6, 71.2)	(57.3, 70.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0052	
	95% CI	(0.8657, 1.1673)	
	Two-sided P-value	0.9454	
AD Duration (years) group: >=26	Baseline, N	125	133
	Week 26, N	125	133
	Number of Subjects with observed Case, N1 (%)	102 (81.6)	117 (88.0)
	Number of Subjects with NRI, N2 (%)	23 (18.4)	16 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Responders, n (%)	82 (65.6)	79 (59.4)
	95% CI	(57.3, 73.9)	(51.1, 67.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1044	
	95% CI	(0.9139, 1.3347)	
	Two-sided P-value	0.3040	
	P-value of interaction	0.4446	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	156	164
	Week 26, N	156	164
	Number of Subjects with observed Case, N1 (%)	124 (79.5)	143 (87.2)
	Number of Subjects with NRI, N2 (%)	32 (20.5)	21 (12.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	90 (57.7)	106 (64.6)
	95% CI	(49.9, 65.4)	(57.3, 72.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8926	
	95% CI	(0.7488, 1.0641)	
	Two-sided P-value	0.2050	
Baseline EASI group: >25	Baseline, N	153	158
	Week 26, N	153	158
	Number of Subjects with observed Case, N1 (%)	134 (87.6)	139 (88.0)
	Number of Subjects with NRI, N2 (%)	19 (12.4)	19 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Responders, n (%)	111 (72.5)	95 (60.1)
	95% CI	(65.5, 79.6)	(52.5, 67.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2066	
	95% CI	(1.0281, 1.4161)	
	Two-sided P-value	0.0215	
	P-value of interaction	0.0129	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	106	115
	Week 26, N	106	115
	Number of Subjects with observed Case, N1 (%)	84 (79.2)	102 (88.7)
	Number of Subjects with NRI, N2 (%)	22 (20.8)	13 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	61 (57.5)	73 (63.5)
	95% CI	(48.1, 67.0)	(54.7, 72.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9066	
	95% CI	(0.7316, 1.1233)	
	Two-sided P-value	0.3698	
Baseline % BSA group: >30-50	Baseline, N	115	110
	Week 26, N	115	110
	Number of Subjects with observed Case, N1 (%)	98 (85.2)	96 (87.3)
	Number of Subjects with NRI, N2 (%)	17 (14.8)	14 (12.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Responders, n (%)	79 (68.7)	68 (61.8)
	95% CI	(60.2, 77.2)	(52.7, 70.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1113	
	95% CI	(0.9173, 1.3462)	
	Two-sided P-value	0.2811	
Baseline % BSA group: >50	Baseline, N	95	100
	Week 26, N	95	100
	Number of Subjects with observed Case, N1 (%)	81 (85.3)	86 (86.0)
	Number of Subjects with NRI, N2 (%)	14 (14.7)	14 (14.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	65 (68.4)	61 (61.0)
	95% CI	(59.1, 77.8)	(51.4, 70.6)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1217	
	95% CI	(0.9111, 1.3809)	
	Two-sided P-value	0.2791	
	P-value of interaction	0.2829	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	151	158
	Week 26, N	151	158
	Number of Subjects with observed Case, N1 (%)	123 (81.5)	142 (89.9)
	Number of Subjects with NRI, N2 (%)	28 (18.5)	16 (10.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	93 (61.6)	95 (60.1)
	95% CI	(53.8, 69.3)	(52.5, 67.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0243	
	95% CI	(0.8566, 1.2249)	
	Two-sided P-value	0.7922	
Prior AD medications: Topical Agents Only	Baseline, N	163	167
	Week 26, N	163	167
	Number of Subjects with observed Case, N1 (%)	138 (84.7)	142 (85.0)
	Number of Subjects with NRI, N2 (%)	25 (15.3)	25 (15.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Responders, n (%)	111 (68.1)	107 (64.1)
	95% CI	(60.9, 75.3)	(56.8, 71.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0628	
	95% CI	(0.9105, 1.2407)	
	Two-sided P-value	0.4401	
	P-value of interaction	0.7597	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	59	86
	Week 26, N	59	86
	Number of Subjects with observed Case, N1 (%)	53 (89.8)	75 (87.2)
	Number of Subjects with NRI, N2 (%)	6 (10.2)	11 (12.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	34 (57.6)	47 (54.7)
	95% CI	(45.0, 70.2)	(44.1, 65.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0545	
	95% CI	(0.7879, 1.4112)	
	Two-sided P-value	0.7214	
Baseline PP-NRS group: >=7	Baseline, N	254	238
	Week 26, N	254	238
	Number of Subjects with observed Case, N1 (%)	208 (81.9)	208 (87.4)
	Number of Subjects with NRI, N2 (%)	46 (18.1)	30 (12.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Skin Pain NRS >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI) (Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Responders, n (%)	169 (66.5)	155 (65.1)
	95% CI	(60.7, 72.3)	(59.1, 71.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0216	
	95% CI	(0.8994, 1.1605)	
	Two-sided P-value	0.7420	
	P-value of interaction	0.8456	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	230	247
	Week 26, N	230	247
	Number of Subjects with observed Case, N1 (%)	183 (79.6)	219 (88.7)
	Number of Subjects with NRI, N2 (%)	47 (20.4)	28 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	89 (38.7)	91 (36.8)
	95% CI	(32.4, 45.0)	(30.8, 42.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0503	
	95% CI	(0.8341, 1.3226)	
	Two-sided P-value	0.6764	
Age (years) group: >=40	Baseline, N	132	118
	Week 26, N	132	118
	Number of Subjects with observed Case, N1 (%)	117 (88.6)	104 (88.1)
	Number of Subjects with NRI, N2 (%)	15 (11.4)	14 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	63 (47.7)	42 (35.6)
	95% CI	(39.2, 56.2)	(27.0, 44.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3409	
	95% CI	(0.9921, 1.8124)	
	Two-sided P-value	0.0564	
	P-value of interaction	0.2069	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	341	354
	Week 26, N	341	354
	Number of Subjects with observed Case, N1 (%)	283 (83.0)	313 (88.4)
	Number of Subjects with NRI, N2 (%)	58 (17.0)	41 (11.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	142 (41.6)	129 (36.4)
	95% CI	(36.4, 46.9)	(31.4, 41.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1427	
	95% CI	(0.9485, 1.3768)	
	Two-sided P-value	0.1604	
Age (years) group: >=65	Baseline, N	21	11
	Week 26, N	21	11
	Number of Subjects with observed Case, N1 (%)	17 (81.0)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	4 (19.0)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Responders, n (%)	10 (47.6)	4 (36.4)
	95% CI	(26.3, 69.0)	(7.9, 64.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3095	
	95% CI	(0.5317, 3.2251)	
	Two-sided P-value	0.5576	
	P-value of interaction	0.7717	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	193	204
	Week 26, N	193	204
	Number of Subjects with observed Case, N1 (%)	168 (87.0)	180 (88.2)
	Number of Subjects with NRI, N2 (%)	25 (13.0)	24 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	77 (39.9)	61 (29.9)
	95% CI	(33.0, 46.8)	(23.6, 36.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3342	
	95% CI	(1.0162, 1.7518)	
	Two-sided P-value	0.0379	
Sex: Female	Baseline, N	169	161
	Week 26, N	169	161
	Number of Subjects with observed Case, N1 (%)	132 (78.1)	143 (88.8)
	Number of Subjects with NRI, N2 (%)	37 (21.9)	18 (11.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	75 (44.4)	72 (44.7)
	95% CI	(36.9, 51.9)	(37.0, 52.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9924	
	95% CI	(0.7800, 1.2625)	
	Two-sided P-value	0.9502	
	P-value of interaction	0.1104	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	269	248
	Week 26, N	269	248
	Number of Subjects with observed Case, N1 (%)	220 (81.8)	219 (88.3)
	Number of Subjects with NRI, N2 (%)	49 (18.2)	29 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	114 (42.4)	95 (38.3)
	95% CI	(36.5, 48.3)	(32.3, 44.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1063	
	95% CI	(0.8962, 1.3657)	
	Two-sided P-value	0.3471	
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	25	26
	Week 26, N	25	26
	Number of Subjects with observed Case, N1 (%)	18 (72.0)	21 (80.8)
	Number of Subjects with NRI, N2 (%)	7 (28.0)	5 (19.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Responders, n (%)	9 (36.0)	6 (23.1)
	95% CI	(17.2, 54.8)	(6.9, 39.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5600	
	95% CI	(0.6503, 3.7423)	
	Two-sided P-value	0.3192	
Race: ASIAN	Baseline, N	62	83
	Week 26, N	62	83
	Number of Subjects with observed Case, N1 (%)	56 (90.3)	75 (90.4)
	Number of Subjects with NRI, N2 (%)	6 (9.7)	8 (9.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	26 (41.9)	31 (37.3)
	95% CI	(29.7, 54.2)	(26.9, 47.8)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1228	
	95% CI	(0.7494, 1.6822)	
	Two-sided P-value	0.5745	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	3 (50.0)	1 (12.5)
	95% CI	(10.0, 90.0)	(0.0, 35.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	4.0000	
	95% CI	(0.5411, 29.5675)	
	Two-sided P-value	0.1744	
	P-value of interaction	0.5541	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	195
	Week 26, N	177	195
	Number of Subjects with observed Case, N1 (%)	141 (79.7)	168 (86.2)
	Number of Subjects with NRI, N2 (%)	36 (20.3)	27 (13.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	75 (42.4)	65 (33.3)
	95% CI	(35.1, 49.7)	(26.7, 39.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2712	
	95% CI	(0.9777, 1.6528)	
	Two-sided P-value	0.0732	
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	130 (86.7)	122 (92.4)
	Number of Subjects with NRI, N2 (%)	20 (13.3)	10 (7.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	61 (40.7)	47 (35.6)
	95% CI	(32.8, 48.5)	(27.4, 43.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1421	
	95% CI	(0.8461, 1.5417)	
	Two-sided P-value	0.3853	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	15 (88.2)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	2 (11.8)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	4 (23.5)	9 (47.4)
	95% CI	(3.4, 43.7)	(24.9, 69.8)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.4967	
	95% CI	(0.1866, 1.3226)	
	Two-sided P-value	0.1614	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	12 (66.7)	12 (63.2)
	95% CI	(44.9, 88.4)	(41.5, 84.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0556	
	95% CI	(0.6571, 1.6956)	
	Two-sided P-value	0.8231	
	P-value of interaction	0.3197	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	216	220
	Week 26, N	216	220
	Number of Subjects with observed Case, N1 (%)	176 (81.5)	194 (88.2)
	Number of Subjects with NRI, N2 (%)	40 (18.5)	26 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	92 (42.6)	71 (32.3)
	95% CI	(36.0, 49.2)	(26.1, 38.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3198	
	95% CI	(1.0318, 1.6882)	
	Two-sided P-value	0.0272	
Baseline disease severity: Severe	Baseline, N	146	145
	Week 26, N	146	145
	Number of Subjects with observed Case, N1 (%)	124 (84.9)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	22 (15.1)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	60 (41.1)	62 (42.8)
	95% CI	(33.1, 49.1)	(34.7, 50.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9611	
	95% CI	(0.7333, 1.2597)	
	Two-sided P-value	0.7738	
	P-value of interaction	0.0893	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	40	51
	Week 26, N	40	51
	Number of Subjects with observed Case, N1 (%)	32 (80.0)	44 (86.3)
	Number of Subjects with NRI, N2 (%)	8 (20.0)	7 (13.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	18 (45.0)	19 (37.3)
	95% CI	(29.6, 60.4)	(24.0, 50.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2079	
	95% CI	(0.7369, 1.9800)	
	Two-sided P-value	0.4538	
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	322	314
	Week 26, N	322	314
	Number of Subjects with observed Case, N1 (%)	268 (83.2)	279 (88.9)
	Number of Subjects with NRI, N2 (%)	54 (16.8)	35 (11.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Responders, n (%)	134 (41.6)	114 (36.3)
	95% CI	(36.2, 47.0)	(31.0, 41.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1462	
	95% CI	(0.9427, 1.3937)	
	Two-sided P-value	0.1711	
	P-value of interaction	0.8468	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	132	136
	Week 26, N	132	136
	Number of Subjects with observed Case, N1 (%)	105 (79.5)	121 (89.0)
	Number of Subjects with NRI, N2 (%)	27 (20.5)	15 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	55 (41.7)	60 (44.1)
	95% CI	(33.3, 50.1)	(35.8, 52.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9444	
	95% CI	(0.7162, 1.2454)	
	Two-sided P-value	0.6855	
Weight (kg): >=70 and <=100	Baseline, N	196	184
	Week 26, N	196	184
	Number of Subjects with observed Case, N1 (%)	168 (85.7)	166 (90.2)
	Number of Subjects with NRI, N2 (%)	28 (14.3)	18 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Responders, n (%)	86 (43.9)	61 (33.2)
	95% CI	(36.9, 50.8)	(26.4, 40.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3235	
	95% CI	(1.0214, 1.7151)	
	Two-sided P-value	0.0340	
Weight (kg): >100	Baseline, N	34	45
	Week 26, N	34	45
	Number of Subjects with observed Case, N1 (%)	27 (79.4)	36 (80.0)
	Number of Subjects with NRI, N2 (%)	7 (20.6)	9 (20.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	11 (32.4)	12 (26.7)
	95% CI	(16.6, 48.1)	(13.7, 39.6)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2132	
	95% CI	(0.6108, 2.4099)	
	Two-sided P-value	0.5809	
	P-value of interaction	0.2141	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	222	220
	Week 26, N	222	220
	Number of Subjects with observed Case, N1 (%)	184 (82.9)	194 (88.2)
	Number of Subjects with NRI, N2 (%)	38 (17.1)	26 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	95 (42.8)	81 (36.8)
	95% CI	(36.3, 49.3)	(30.4, 43.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1623	
	95% CI	(0.9231, 1.4635)	
	Two-sided P-value	0.2009	
AD Duration (years) group: >=26	Baseline, N	140	145
	Week 26, N	140	145
	Number of Subjects with observed Case, N1 (%)	116 (82.9)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	24 (17.1)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Responders, n (%)	57 (40.7)	52 (35.9)
	95% CI	(32.6, 48.9)	(28.1, 43.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1353	
	95% CI	(0.8448, 1.5257)	
	Two-sided P-value	0.4000	
	P-value of interaction	0.9023	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	181	183
	Week 26, N	181	183
	Number of Subjects with observed Case, N1 (%)	144 (79.6)	160 (87.4)
	Number of Subjects with NRI, N2 (%)	37 (20.4)	23 (12.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	75 (41.4)	65 (35.5)
	95% CI	(34.3, 48.6)	(28.6, 42.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1666	
	95% CI	(0.8986, 1.5145)	
	Two-sided P-value	0.2472	
Baseline EASI group: >25	Baseline, N	172	174
	Week 26, N	172	174
	Number of Subjects with observed Case, N1 (%)	149 (86.6)	156 (89.7)
	Number of Subjects with NRI, N2 (%)	23 (13.4)	18 (10.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Responders, n (%)	71 (41.3)	64 (36.8)
	95% CI	(33.9, 48.6)	(29.6, 43.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1223	
	95% CI	(0.8618, 1.4614)	
	Two-sided P-value	0.3918	
	P-value of interaction	0.8380	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	122	133
	Week 26, N	122	133
	Number of Subjects with observed Case, N1 (%)	98 (80.3)	120 (90.2)
	Number of Subjects with NRI, N2 (%)	24 (19.7)	13 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	55 (45.1)	53 (39.8)
	95% CI	(36.3, 53.9)	(31.5, 48.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1313	
	95% CI	(0.8497, 1.5063)	
	Two-sided P-value	0.3983	
Baseline % BSA group: >30-50	Baseline, N	132	121
	Week 26, N	132	121
	Number of Subjects with observed Case, N1 (%)	111 (84.1)	106 (87.6)
	Number of Subjects with NRI, N2 (%)	21 (15.9)	15 (12.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Responders, n (%)	53 (40.2)	36 (29.8)
	95% CI	(31.8, 48.5)	(21.6, 37.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3495	
	95% CI	(0.9567, 1.9036)	
	Two-sided P-value	0.0877	
Baseline % BSA group: >50	Baseline, N	108	111
	Week 26, N	108	111
	Number of Subjects with observed Case, N1 (%)	91 (84.3)	97 (87.4)
	Number of Subjects with NRI, N2 (%)	17 (15.7)	14 (12.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	44 (40.7)	44 (39.6)
	95% CI	(31.5, 50.0)	(30.5, 48.7)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0278	
	95% CI	(0.7440, 1.4199)	
	Two-sided P-value	0.8680	
	P-value of interaction	0.5201	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	172	176
	Week 26, N	172	176
	Number of Subjects with observed Case, N1 (%)	140 (81.4)	160 (90.9)
	Number of Subjects with NRI, N2 (%)	32 (18.6)	16 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	78 (45.3)	70 (39.8)
	95% CI	(37.9, 52.8)	(32.5, 47.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1402	
	95% CI	(0.8925, 1.4566)	
	Two-sided P-value	0.2937	
Prior AD medications: Topical Agents Only	Baseline, N	188	189
	Week 26, N	188	189
	Number of Subjects with observed Case, N1 (%)	158 (84.0)	163 (86.2)
	Number of Subjects with NRI, N2 (%)	30 (16.0)	26 (13.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Responders, n (%)	72 (38.3)	63 (33.3)
	95% CI	(31.3, 45.2)	(26.6, 40.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1489	
	95% CI	(0.8760, 1.5069)	
	Two-sided P-value	0.3158	
	P-value of interaction	0.9673	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	83	105
	Week 26, N	83	105
	Number of Subjects with observed Case, N1 (%)	73 (88.0)	94 (89.5)
	Number of Subjects with NRI, N2 (%)	10 (12.0)	11 (10.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	36 (43.4)	45 (42.9)
	95% CI	(32.7, 54.0)	(33.4, 52.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0120	
	95% CI	(0.7272, 1.4084)	
	Two-sided P-value	0.9434	
Baseline PP-NRS group: >=7	Baseline, N	274	259
	Week 26, N	274	259
	Number of Subjects with observed Case, N1 (%)	225 (82.1)	228 (88.0)
	Number of Subjects with NRI, N2 (%)	49 (17.9)	31 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Responders, n (%)	114 (41.6)	88 (34.0)
	95% CI	(35.8, 47.4)	(28.2, 39.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2245	
	95% CI	(0.9825, 1.5262)	
	Two-sided P-value	0.0714	
	P-value of interaction	0.3469	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	230	247
	Week 26, N	230	247
	Number of Subjects with observed Case, N1 (%)	183 (79.6)	219 (88.7)
	Number of Subjects with NRI, N2 (%)	47 (20.4)	28 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	42 (18.3)	32 (13.0)
	95% CI	(13.3, 23.3)	(8.8, 17.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4095	
	95% CI	(0.9230, 2.1525)	
	Two-sided P-value	0.1121	
Age (years) group: >=40	Baseline, N	132	118
	Week 26, N	132	118
	Number of Subjects with observed Case, N1 (%)	117 (88.6)	104 (88.1)
	Number of Subjects with NRI, N2 (%)	15 (11.4)	14 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	38 (28.8)	20 (16.9)
	95% CI	(21.1, 36.5)	(10.2, 23.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6985	
	95% CI	(1.0498, 2.7480)	
	Two-sided P-value	0.0309	
	P-value of interaction	0.5685	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	341	354
	Week 26, N	341	354
	Number of Subjects with observed Case, N1 (%)	283 (83.0)	313 (88.4)
	Number of Subjects with NRI, N2 (%)	58 (17.0)	41 (11.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	75 (22.0)	52 (14.7)
	95% CI	(17.6, 26.4)	(11.0, 18.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4973	
	95% CI	(1.0863, 2.0638)	
	Two-sided P-value	0.0137	
Age (years) group: >=65	Baseline, N	21	11
	Week 26, N	21	11
	Number of Subjects with observed Case, N1 (%)	17 (81.0)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	4 (19.0)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Responders, n (%)	5 (23.8)	0
	95% CI	(5.6, 42.0)	(0.0, 28.5)
	P-value of interaction	0.3700	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	193	204
	Week 26, N	193	204
	Number of Subjects with observed Case, N1 (%)	168 (87.0)	180 (88.2)
	Number of Subjects with NRI, N2 (%)	25 (13.0)	24 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	43 (22.3)	23 (11.3)
	95% CI	(16.4, 28.2)	(6.9, 15.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.9761	
	95% CI	(1.2394, 3.1507)	
	Two-sided P-value	0.0042	
Sex: Female	Baseline, N	169	161
	Week 26, N	169	161
	Number of Subjects with observed Case, N1 (%)	132 (78.1)	143 (88.8)
	Number of Subjects with NRI, N2 (%)	37 (21.9)	18 (11.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	37 (21.9)	29 (18.0)
	95% CI	(15.7, 28.1)	(12.1, 23.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2155	
	95% CI	(0.7863, 1.8789)	
	Two-sided P-value	0.3799	
	P-value of interaction	0.1356	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	269	248
	Week 26, N	269	248
	Number of Subjects with observed Case, N1 (%)	220 (81.8)	219 (88.3)
	Number of Subjects with NRI, N2 (%)	49 (18.2)	29 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	58 (21.6)	39 (15.7)
	95% CI	(16.6, 26.5)	(11.2, 20.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3711	
	95% CI	(0.9495, 1.9797)	
	Two-sided P-value	0.0922	
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	25	26
	Week 26, N	25	26
	Number of Subjects with observed Case, N1 (%)	18 (72.0)	21 (80.8)
	Number of Subjects with NRI, N2 (%)	7 (28.0)	5 (19.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Responders, n (%)	5 (20.0)	1 (3.8)
	95% CI	(4.3, 35.7)	(0.0, 11.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	5.2000	
	95% CI	(0.6525, 41.4428)	
	Two-sided P-value	0.1195	
Race: ASIAN	Baseline, N	62	83
	Week 26, N	62	83
	Number of Subjects with observed Case, N1 (%)	56 (90.3)	75 (90.4)
	Number of Subjects with NRI, N2 (%)	6 (9.7)	8 (9.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	15 (24.2)	11 (13.3)
	95% CI	(13.5, 34.9)	(6.0, 20.5)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.8255	
	95% CI	(0.9020, 3.6947)	
	Two-sided P-value	0.0943	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	2 (33.3)	1 (12.5)
	95% CI	(0.0, 71.1)	(0.0, 35.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.6667	
	95% CI	(0.3092, 22.9956)	
	Two-sided P-value	0.3722	
	P-value of interaction	0.5375	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	195
	Week 26, N	177	195
	Number of Subjects with observed Case, N1 (%)	141 (79.7)	168 (86.2)
	Number of Subjects with NRI, N2 (%)	36 (20.3)	27 (13.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	44 (24.9)	22 (11.3)
	95% CI	(18.5, 31.2)	(6.8, 15.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.2034	
	95% CI	(1.3777, 3.5240)	
	Two-sided P-value	0.0010	
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	130 (86.7)	122 (92.4)
	Number of Subjects with NRI, N2 (%)	20 (13.3)	10 (7.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	27 (18.0)	19 (14.4)
	95% CI	(11.9, 24.1)	(8.4, 20.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2505	
	95% CI	(0.7300, 2.1422)	
	Two-sided P-value	0.4156	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	15 (88.2)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	2 (11.8)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	1 (5.9)	4 (21.1)
	95% CI	(0.0, 17.1)	(2.7, 39.4)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.2794	
	95% CI	(0.0345, 2.2620)	
	Two-sided P-value	0.2321	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	8 (44.4)	7 (36.8)
	95% CI	(21.5, 67.4)	(15.2, 58.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2063	
	95% CI	(0.5512, 2.6400)	
	Two-sided P-value	0.6387	
	P-value of interaction	0.1251	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	216	220
	Week 26, N	216	220
	Number of Subjects with observed Case, N1 (%)	176 (81.5)	194 (88.2)
	Number of Subjects with NRI, N2 (%)	40 (18.5)	26 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	50 (23.1)	30 (13.6)
	95% CI	(17.5, 28.8)	(9.1, 18.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6975	
	95% CI	(1.1245, 2.5626)	
	Two-sided P-value	0.0118	
Baseline disease severity: Severe	Baseline, N	146	145
	Week 26, N	146	145
	Number of Subjects with observed Case, N1 (%)	124 (84.9)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	22 (15.1)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	30 (20.5)	22 (15.2)
	95% CI	(14.0, 27.1)	(9.3, 21.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3543	
	95% CI	(0.8215, 2.2325)	
	Two-sided P-value	0.2344	
	P-value of interaction	0.4942	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	40	51
	Week 26, N	40	51
	Number of Subjects with observed Case, N1 (%)	32 (80.0)	44 (86.3)
	Number of Subjects with NRI, N2 (%)	8 (20.0)	7 (13.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	7 (17.5)	4 (7.8)
	95% CI	(5.7, 29.3)	(0.5, 15.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.2313	
	95% CI	(0.7018, 7.0936)	
	Two-sided P-value	0.1738	
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	322	314
	Week 26, N	322	314
	Number of Subjects with observed Case, N1 (%)	268 (83.2)	279 (88.9)
	Number of Subjects with NRI, N2 (%)	54 (16.8)	35 (11.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Responders, n (%)	73 (22.7)	48 (15.3)
	95% CI	(18.1, 27.2)	(11.3, 19.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4830	
	95% CI	(1.0669, 2.0616)	
	Two-sided P-value	0.0190	
	P-value of interaction	0.5056	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	132	136
	Week 26, N	132	136
	Number of Subjects with observed Case, N1 (%)	105 (79.5)	121 (89.0)
	Number of Subjects with NRI, N2 (%)	27 (20.5)	15 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	24 (18.2)	22 (16.2)
	95% CI	(11.6, 24.8)	(10.0, 22.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1240	
	95% CI	(0.6638, 1.9031)	
	Two-sided P-value	0.6636	
Weight (kg): >=70 and <=100	Baseline, N	196	184
	Week 26, N	196	184
	Number of Subjects with observed Case, N1 (%)	168 (85.7)	166 (90.2)
	Number of Subjects with NRI, N2 (%)	28 (14.3)	18 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Responders, n (%)	50 (25.5)	26 (14.1)
	95% CI	(19.4, 31.6)	(9.1, 19.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.8053	
	95% CI	(1.1755, 2.7727)	
	Two-sided P-value	0.0070	
Weight (kg): >100	Baseline, N	34	45
	Week 26, N	34	45
	Number of Subjects with observed Case, N1 (%)	27 (79.4)	36 (80.0)
	Number of Subjects with NRI, N2 (%)	7 (20.6)	9 (20.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (17.6)	4 (8.9)
	95% CI	(4.8, 30.5)	(0.6, 17.2)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.9853	
	95% CI	(0.6075, 6.4879)	
	Two-sided P-value	0.2564	
	P-value of interaction	0.3544	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	222	220
	Week 26, N	222	220
	Number of Subjects with observed Case, N1 (%)	184 (82.9)	194 (88.2)
	Number of Subjects with NRI, N2 (%)	38 (17.1)	26 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	48 (21.6)	29 (13.2)
	95% CI	(16.2, 27.0)	(8.7, 17.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6403	
	95% CI	(1.0760, 2.5004)	
	Two-sided P-value	0.0214	
AD Duration (years) group: >=26	Baseline, N	140	145
	Week 26, N	140	145
	Number of Subjects with observed Case, N1 (%)	116 (82.9)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	24 (17.1)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Responders, n (%)	32 (22.9)	23 (15.9)
	95% CI	(15.9, 29.8)	(9.9, 21.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4410	
	95% CI	(0.8891, 2.3354)	
	Two-sided P-value	0.1381	
	P-value of interaction	0.6921	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	181	183
	Week 26, N	181	183
	Number of Subjects with observed Case, N1 (%)	144 (79.6)	160 (87.4)
	Number of Subjects with NRI, N2 (%)	37 (20.4)	23 (12.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	46 (25.4)	27 (14.8)
	95% CI	(19.1, 31.8)	(9.6, 19.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.7225	
	95% CI	(1.1223, 2.6439)	
	Two-sided P-value	0.0129	
Baseline EASI group: >25	Baseline, N	172	174
	Week 26, N	172	174
	Number of Subjects with observed Case, N1 (%)	149 (86.6)	156 (89.7)
	Number of Subjects with NRI, N2 (%)	23 (13.4)	18 (10.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Responders, n (%)	33 (19.2)	23 (13.2)
	95% CI	(13.3, 25.1)	(8.2, 18.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4515	
	95% CI	(0.8902, 2.3666)	
	Two-sided P-value	0.1353	
	P-value of interaction	0.6057	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	122	133
	Week 26, N	122	133
	Number of Subjects with observed Case, N1 (%)	98 (80.3)	120 (90.2)
	Number of Subjects with NRI, N2 (%)	24 (19.7)	13 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	29 (23.8)	25 (18.8)
	95% CI	(16.2, 31.3)	(12.2, 25.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2646	
	95% CI	(0.7863, 2.0338)	
	Two-sided P-value	0.3329	
Baseline % BSA group: >30-50	Baseline, N	132	121
	Week 26, N	132	121
	Number of Subjects with observed Case, N1 (%)	111 (84.1)	106 (87.6)
	Number of Subjects with NRI, N2 (%)	21 (15.9)	15 (12.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Responders, n (%)	30 (22.7)	13 (10.7)
	95% CI	(15.6, 29.9)	(5.2, 16.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.1154	
	95% CI	(1.1583, 3.8631)	
	Two-sided P-value	0.0148	
Baseline % BSA group: >50	Baseline, N	108	111
	Week 26, N	108	111
	Number of Subjects with observed Case, N1 (%)	91 (84.3)	97 (87.4)
	Number of Subjects with NRI, N2 (%)	17 (15.7)	14 (12.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	21 (19.4)	14 (12.6)
	95% CI	(12.0, 26.9)	(6.4, 18.8)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5417	
	95% CI	(0.8275, 2.8722)	
	Two-sided P-value	0.1727	
	P-value of interaction	0.4215	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	172	176
	Week 26, N	172	176
	Number of Subjects with observed Case, N1 (%)	140 (81.4)	160 (90.9)
	Number of Subjects with NRI, N2 (%)	32 (18.6)	16 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	42 (24.4)	30 (17.0)
	95% CI	(18.0, 30.8)	(11.5, 22.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4326	
	95% CI	(0.9424, 2.1776)	
	Two-sided P-value	0.0925	
Prior AD medications: Topical Agents Only	Baseline, N	188	189
	Week 26, N	188	189
	Number of Subjects with observed Case, N1 (%)	158 (84.0)	163 (86.2)
	Number of Subjects with NRI, N2 (%)	30 (16.0)	26 (13.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Responders, n (%)	38 (20.2)	22 (11.6)
	95% CI	(14.5, 26.0)	(7.1, 16.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.7365	
	95% CI	(1.0694, 2.8195)	
	Two-sided P-value	0.0257	
	P-value of interaction	0.5561	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	83	105
	Week 26, N	83	105
	Number of Subjects with observed Case, N1 (%)	73 (88.0)	94 (89.5)
	Number of Subjects with NRI, N2 (%)	10 (12.0)	11 (10.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	20 (24.1)	16 (15.2)
	95% CI	(14.9, 33.3)	(8.4, 22.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5813	
	95% CI	(0.8757, 2.8556)	
	Two-sided P-value	0.1286	
Baseline PP-NRS group: >=7	Baseline, N	274	259
	Week 26, N	274	259
	Number of Subjects with observed Case, N1 (%)	225 (82.1)	228 (88.0)
	Number of Subjects with NRI, N2 (%)	49 (17.9)	31 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Responders, n (%)	59 (21.5)	36 (13.9)
	95% CI	(16.7, 26.4)	(9.7, 18.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5492	
	95% CI	(1.0614, 2.2610)	
	Two-sided P-value	0.0233	
	P-value of interaction	0.9542	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	212	229
	Week 26, N	212	229
	Number of Subjects with observed Case, N1 (%)	169 (79.7)	203 (88.6)
	Number of Subjects with NRI, N2 (%)	43 (20.3)	26 (11.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	153 (72.2)	182 (79.5)
	95% CI	(66.1, 78.2)	(74.2, 84.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9081	
	95% CI	(0.8164, 1.0100)	
	Two-sided P-value	0.0757	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Baseline, N	117	104
	Week 26, N	117	104
	Number of Subjects with observed Case, N1 (%)	104 (88.9)	92 (88.5)
	Number of Subjects with NRI, N2 (%)	13 (11.1)	12 (11.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	100 (85.5)	83 (79.8)
	95% CI	(79.1, 91.9)	(72.1, 87.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0710	
	95% CI	(0.9478, 1.2101)	
	Two-sided P-value	0.2715	
	P-value of interaction	0.0459	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	314	322
	Week 26, N	314	322
	Number of Subjects with observed Case, N1 (%)	260 (82.8)	285 (88.5)
	Number of Subjects with NRI, N2 (%)	54 (17.2)	37 (11.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	240 (76.4)	255 (79.2)
	95% CI	(71.7, 81.1)	(74.8, 83.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9652	
	95% CI	(0.8882, 1.0488)	
	Two-sided P-value	0.4029	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Baseline, N	15	11
	Week 26, N	15	11
	Number of Subjects with observed Case, N1 (%)	13 (86.7)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	2 (13.3)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	13 (86.7)	10 (90.9)
	95% CI	(69.5, 100.0)	(73.9, 100.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9533	
	95% CI	(0.7259, 1.2521)	
	Two-sided P-value	0.7312	
	P-value of interaction	0.9325	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	170	186
	Week 26, N	170	186
	Number of Subjects with observed Case, N1 (%)	149 (87.6)	164 (88.2)
	Number of Subjects with NRI, N2 (%)	21 (12.4)	22 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	137 (80.6)	145 (78.0)
	95% CI	(74.6, 86.5)	(72.0, 83.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0338	
	95% CI	(0.9296, 1.1496)	
	Two-sided P-value	0.5402	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Baseline, N	159	147
	Week 26, N	159	147
	Number of Subjects with observed Case, N1 (%)	124 (78.0)	131 (89.1)
	Number of Subjects with NRI, N2 (%)	35 (22.0)	16 (10.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	116 (73.0)	120 (81.6)
	95% CI	(66.1, 79.9)	(75.4, 87.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8937	
	95% CI	(0.7912, 1.0095)	
	Two-sided P-value	0.0706	
	P-value of interaction	0.0775	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	244	225
	Week 26, N	244	225
	Number of Subjects with observed Case, N1 (%)	200 (82.0)	199 (88.4)
	Number of Subjects with NRI, N2 (%)	44 (18.0)	26 (11.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	187 (76.6)	181 (80.4)
	95% CI	(71.3, 81.9)	(75.3, 85.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9527	
	95% CI	(0.8667, 1.0472)	
	Two-sided P-value	0.3154	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	22	20
	Week 26, N	22	20
	Number of Subjects with observed Case, N1 (%)	16 (72.7)	16 (80.0)
	Number of Subjects with NRI, N2 (%)	6 (27.3)	4 (20.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	13 (59.1)	15 (75.0)
	95% CI	(38.5, 79.6)	(56.0, 94.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.7879	
	95% CI	(0.5125, 1.2112)	
	Two-sided P-value	0.2772	
Race: ASIAN	Baseline, N	57	80
	Week 26, N	57	80
	Number of Subjects with observed Case, N1 (%)	51 (89.5)	72 (90.0)
	Number of Subjects with NRI, N2 (%)	6 (10.5)	8 (10.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: ASIAN	Responders, n (%)	47 (82.5)	63 (78.8)
	95% CI	(72.6, 92.3)	(69.8, 87.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0471	
	95% CI	(0.8876, 1.2352)	
	Two-sided P-value	0.5854	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (100.0)	6 (75.0)
	95% CI	(54.1, 100.0)	(45.0, 100.0)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3333	
	95% CI	(0.8937, 1.9893)	
	Two-sided P-value	0.1587	
	P-value of interaction	0.4097	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	153	173
	Week 26, N	153	173
	Number of Subjects with observed Case, N1 (%)	122 (79.7)	149 (86.1)
	Number of Subjects with NRI, N2 (%)	31 (20.3)	24 (13.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	114 (74.5)	134 (77.5)
	95% CI	(67.6, 81.4)	(71.2, 83.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9620	
	95% CI	(0.8509, 1.0875)	
	Two-sided P-value	0.5355	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Baseline, N	142	125
	Week 26, N	142	125
	Number of Subjects with observed Case, N1 (%)	123 (86.6)	115 (92.0)
	Number of Subjects with NRI, N2 (%)	19 (13.4)	10 (8.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	113 (79.6)	105 (84.0)
	95% CI	(72.9, 86.2)	(77.6, 90.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9474	
	95% CI	(0.8460, 1.0608)	
	Two-sided P-value	0.3487	
Region of enrollment: Asia	Baseline, N	16	19
	Week 26, N	16	19
	Number of Subjects with observed Case, N1 (%)	14 (87.5)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	2 (12.5)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Asia	Responders, n (%)	13 (81.3)	16 (84.2)
	95% CI	(62.1, 100.0)	(67.8, 100.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9648	
	95% CI	(0.7109, 1.3096)	
	Two-sided P-value	0.8184	
Region of enrollment: Latin America	Baseline, N	18	16
	Week 26, N	18	16
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	13 (81.3)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	3 (18.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	13 (72.2)	10 (62.5)
	95% CI	(51.5, 92.9)	(38.8, 86.2)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1556	
	95% CI	(0.7182, 1.8592)	
	Two-sided P-value	0.5512	
	P-value of interaction	0.8875	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	190	194
	Week 26, N	190	194
	Number of Subjects with observed Case, N1 (%)	156 (82.1)	171 (88.1)
	Number of Subjects with NRI, N2 (%)	34 (17.9)	23 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	139 (73.2)	150 (77.3)
	95% CI	(66.9, 79.5)	(71.4, 83.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9462	
	95% CI	(0.8434, 1.0615)	
	Two-sided P-value	0.3457	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Baseline, N	139	139
	Week 26, N	139	139
	Number of Subjects with observed Case, N1 (%)	117 (84.2)	124 (89.2)
	Number of Subjects with NRI, N2 (%)	22 (15.8)	15 (10.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	114 (82.0)	115 (82.7)
	95% CI	(75.6, 88.4)	(76.5, 89.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9913	
	95% CI	(0.8891, 1.1052)	
	Two-sided P-value	0.8749	
	P-value of interaction	0.5640	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	39	47
	Week 26, N	39	47
	Number of Subjects with observed Case, N1 (%)	31 (79.5)	40 (85.1)
	Number of Subjects with NRI, N2 (%)	8 (20.5)	7 (14.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	28 (71.8)	35 (74.5)
	95% CI	(57.7, 85.9)	(62.0, 86.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9641	
	95% CI	(0.7446, 1.2482)	
	Two-sided P-value	0.7815	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	290	286
	Week 26, N	290	286
	Number of Subjects with observed Case, N1 (%)	242 (83.4)	255 (89.2)
	Number of Subjects with NRI, N2 (%)	48 (16.6)	31 (10.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	225 (77.6)	230 (80.4)
	95% CI	(72.8, 82.4)	(75.8, 85.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9648	
	95% CI	(0.8868, 1.0496)	
	Two-sided P-value	0.4040	
	P-value of interaction	0.9960	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	123	125
	Week 26, N	123	125
	Number of Subjects with observed Case, N1 (%)	97 (78.9)	110 (88.0)
	Number of Subjects with NRI, N2 (%)	26 (21.1)	15 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	91 (74.0)	102 (81.6)
	95% CI	(66.2, 81.7)	(74.8, 88.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9067	
	95% CI	(0.7931, 1.0365)	
	Two-sided P-value	0.1513	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Baseline, N	179	167
	Week 26, N	179	167
	Number of Subjects with observed Case, N1 (%)	156 (87.2)	150 (89.8)
	Number of Subjects with NRI, N2 (%)	23 (12.8)	17 (10.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	145 (81.0)	133 (79.6)
	95% CI	(75.3, 86.8)	(73.5, 85.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0171	
	95% CI	(0.9162, 1.1291)	
	Two-sided P-value	0.7499	
Weight (kg): >100	Baseline, N	27	41
	Week 26, N	27	41
	Number of Subjects with observed Case, N1 (%)	20 (74.1)	35 (85.4)
	Number of Subjects with NRI, N2 (%)	7 (25.9)	6 (14.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >100	Responders, n (%)	17 (63.0)	30 (73.2)
	95% CI	(44.7, 81.2)	(59.6, 86.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8605	
	95% CI	(0.6103, 1.2133)	
	Two-sided P-value	0.3914	
	P-value of interaction	0.3275	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	198	198
	Week 26, N	198	198
	Number of Subjects with observed Case, N1 (%)	165 (83.3)	174 (87.9)
	Number of Subjects with NRI, N2 (%)	33 (16.7)	24 (12.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	147 (74.2)	159 (80.3)
	95% CI	(68.2, 80.3)	(74.8, 85.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9245	
	95% CI	(0.8306, 1.0291)	
	Two-sided P-value	0.1513	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Baseline, N	131	135
	Week 26, N	131	135
	Number of Subjects with observed Case, N1 (%)	108 (82.4)	121 (89.6)
	Number of Subjects with NRI, N2 (%)	23 (17.6)	14 (10.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	106 (80.9)	106 (78.5)
	95% CI	(74.2, 87.6)	(71.6, 85.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0305	
	95% CI	(0.9129, 1.1634)	
	Two-sided P-value	0.6268	
	P-value of interaction	0.1886	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	157	163
	Week 26, N	157	163
	Number of Subjects with observed Case, N1 (%)	126 (80.3)	143 (87.7)
	Number of Subjects with NRI, N2 (%)	31 (19.7)	20 (12.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	112 (71.3)	123 (75.5)
	95% CI	(64.3, 78.4)	(68.9, 82.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9454	
	95% CI	(0.8282, 1.0791)	
	Two-sided P-value	0.4051	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Baseline, N	165	163
	Week 26, N	165	163
	Number of Subjects with observed Case, N1 (%)	142 (86.1)	146 (89.6)
	Number of Subjects with NRI, N2 (%)	23 (13.9)	17 (10.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	136 (82.4)	137 (84.0)
	95% CI	(76.6, 88.2)	(78.4, 89.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9807	
	95% CI	(0.8899, 1.0807)	
	Two-sided P-value	0.6937	
	P-value of interaction	0.6615	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	101	121
	Week 26, N	101	121
	Number of Subjects with observed Case, N1 (%)	81 (80.2)	109 (90.1)
	Number of Subjects with NRI, N2 (%)	20 (19.8)	12 (9.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	72 (71.3)	94 (77.7)
	95% CI	(62.5, 80.1)	(70.3, 85.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9176	
	95% CI	(0.7848, 1.0729)	
	Two-sided P-value	0.2812	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Baseline, N	125	109
	Week 26, N	125	109
	Number of Subjects with observed Case, N1 (%)	106 (84.8)	96 (88.1)
	Number of Subjects with NRI, N2 (%)	19 (15.2)	13 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	98 (78.4)	86 (78.9)
	95% CI	(71.2, 85.6)	(71.2, 86.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9937	
	95% CI	(0.8693, 1.1359)	
	Two-sided P-value	0.9259	
Baseline % BSA group: >50	Baseline, N	103	103
	Week 26, N	103	103
	Number of Subjects with observed Case, N1 (%)	86 (83.5)	90 (87.4)
	Number of Subjects with NRI, N2 (%)	17 (16.5)	13 (12.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >50	Responders, n (%)	83 (80.6)	85 (82.5)
	95% CI	(72.9, 88.2)	(75.2, 89.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9765	
	95% CI	(0.8575, 1.1120)	
	Two-sided P-value	0.7195	
	P-value of interaction	0.7363	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	159	159
	Week 26, N	159	159
	Number of Subjects with observed Case, N1 (%)	130 (81.8)	144 (90.6)
	Number of Subjects with NRI, N2 (%)	29 (18.2)	15 (9.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	120 (75.5)	128 (80.5)
	95% CI	(68.8, 82.2)	(74.3, 86.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9375	
	95% CI	(0.8339, 1.0539)	
	Two-sided P-value	0.2799	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Baseline, N	168	174
	Week 26, N	168	174
	Number of Subjects with observed Case, N1 (%)	141 (83.9)	151 (86.8)
	Number of Subjects with NRI, N2 (%)	27 (16.1)	23 (13.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	131 (78.0)	137 (78.7)
	95% CI	(71.7, 84.2)	(72.7, 84.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9904	
	95% CI	(0.8859, 1.1071)	
	Two-sided P-value	0.8647	
	P-value of interaction	0.5060	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	68	88
	Week 26, N	68	88
	Number of Subjects with observed Case, N1 (%)	59 (86.8)	79 (89.8)
	Number of Subjects with NRI, N2 (%)	9 (13.2)	9 (10.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	52 (76.5)	71 (80.7)
	95% CI	(66.4, 86.6)	(72.4, 88.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9478	
	95% CI	(0.8022, 1.1199)	
	Two-sided P-value	0.5288	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Sleep Loss >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Baseline, N	258	245
	Week 26, N	258	245
	Number of Subjects with observed Case, N1 (%)	212 (82.2)	216 (88.2)
	Number of Subjects with NRI, N2 (%)	46 (17.8)	29 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	199 (77.1)	194 (79.2)
	95% CI	(72.0, 82.3)	(74.1, 84.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9741	
	95% CI	(0.8881, 1.0684)	
	Two-sided P-value	0.5776	
	P-value of interaction	0.7786	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	230	247
	Week 26, N	230	247
	Number of Subjects with observed Case, N1 (%)	183 (79.6)	219 (88.7)
	Number of Subjects with NRI, N2 (%)	47 (20.4)	28 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	162 (70.4)	196 (79.4)
	95% CI	(64.5, 76.3)	(74.3, 84.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8876	
	95% CI	(0.7990, 0.9860)	
	Two-sided P-value	0.0263	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Baseline, N	132	118
	Week 26, N	132	118
	Number of Subjects with observed Case, N1 (%)	117 (88.6)	104 (88.1)
	Number of Subjects with NRI, N2 (%)	15 (11.4)	14 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	111 (84.1)	98 (83.1)
	95% CI	(77.9, 90.3)	(76.3, 89.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0125	
	95% CI	(0.9068, 1.1305)	
	Two-sided P-value	0.8249	
	P-value of interaction	0.0903	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <65	Baseline, N	341	354
	Week 26, N	341	354
	Number of Subjects with observed Case, N1 (%)	283 (83.0)	313 (88.4)
	Number of Subjects with NRI, N2 (%)	58 (17.0)	41 (11.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	257 (75.4)	285 (80.5)
	95% CI	(70.8, 79.9)	(76.4, 84.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9361	
	95% CI	(0.8647, 1.0135)	
	Two-sided P-value	0.1034	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Age group (<65, >=65)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=65	Baseline, N	21	11
	Week 26, N	21	11
	Number of Subjects with observed Case, N1 (%)	17 (81.0)	10 (90.9)
	Number of Subjects with NRI, N2 (%)	4 (19.0)	1 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	16 (76.2)	9 (81.8)
	95% CI	(58.0, 94.4)	(59.0, 100.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9312	
	95% CI	(0.6451, 1.3443)	
	Two-sided P-value	0.7036	
	P-value of interaction	0.9781	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	193	204
	Week 26, N	193	204
	Number of Subjects with observed Case, N1 (%)	168 (87.0)	180 (88.2)
	Number of Subjects with NRI, N2 (%)	25 (13.0)	24 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	149 (77.2)	163 (79.9)
	95% CI	(71.3, 83.1)	(74.4, 85.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9662	
	95% CI	(0.8716, 1.0711)	
	Two-sided P-value	0.5132	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Baseline, N	169	161
	Week 26, N	169	161
	Number of Subjects with observed Case, N1 (%)	132 (78.1)	143 (88.8)
	Number of Subjects with NRI, N2 (%)	37 (21.9)	18 (11.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	124 (73.4)	131 (81.4)
	95% CI	(66.7, 80.0)	(75.4, 87.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9018	
	95% CI	(0.8021, 1.0138)	
	Two-sided P-value	0.0835	
	P-value of interaction	0.3857	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: WHITE	Baseline, N	269	248
	Week 26, N	269	248
	Number of Subjects with observed Case, N1 (%)	220 (81.8)	219 (88.3)
	Number of Subjects with NRI, N2 (%)	49 (18.2)	29 (11.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	202 (75.1)	204 (82.3)
	95% CI	(69.9, 80.3)	(77.5, 87.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9129	
	95% CI	(0.8344, 0.9987)	
	Two-sided P-value	0.0469	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: BLACK OR AFRICAN AMERICAN	Baseline, N	25	26
	Week 26, N	25	26
	Number of Subjects with observed Case, N1 (%)	18 (72.0)	21 (80.8)
	Number of Subjects with NRI, N2 (%)	7 (28.0)	5 (19.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	17 (68.0)	17 (65.4)
	95% CI	(49.7, 86.3)	(47.1, 83.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0400	
	95% CI	(0.7056, 1.5330)	
	Two-sided P-value	0.8429	
Race: ASIAN	Baseline, N	62	83
	Week 26, N	62	83
	Number of Subjects with observed Case, N1 (%)	56 (90.3)	75 (90.4)
	Number of Subjects with NRI, N2 (%)	6 (9.7)	8 (9.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Race: ASIAN	Responders, n (%)	48 (77.4)	67 (80.7)
	95% CI	(67.0, 87.8)	(72.2, 89.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9591	
	95% CI	(0.8086, 1.1375)	
	Two-sided P-value	0.6313	
Race: OTHER	Baseline, N	6	8
	Week 26, N	6	8
	Number of Subjects with observed Case, N1 (%)	6 (100.0)	8 (100.0)
	Number of Subjects with NRI, N2 (%)	0	0
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (100.0)	6 (75.0)
	95% CI	(54.1, 100.0)	(45.0, 100.0)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Race

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3333	
	95% CI	(0.8937, 1.9893)	
	Two-sided P-value	0.1587	
	P-value of interaction	0.5656	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	195
	Week 26, N	177	195
	Number of Subjects with observed Case, N1 (%)	141 (79.7)	168 (86.2)
	Number of Subjects with NRI, N2 (%)	36 (20.3)	27 (13.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	132 (74.6)	153 (78.5)
	95% CI	(68.2, 81.0)	(72.7, 84.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9505	
	95% CI	(0.8488, 1.0644)	
	Two-sided P-value	0.3791	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	130 (86.7)	122 (92.4)
	Number of Subjects with NRI, N2 (%)	20 (13.3)	10 (7.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	115 (76.7)	110 (83.3)
	95% CI	(69.9, 83.4)	(77.0, 89.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9200	
	95% CI	(0.8187, 1.0339)	
	Two-sided P-value	0.1613	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	15 (88.2)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	2 (11.8)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Asia	Responders, n (%)	12 (70.6)	18 (94.7)
	95% CI	(48.9, 92.2)	(84.7, 100.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.7451	
	95% CI	(0.5386, 1.0309)	
	Two-sided P-value	0.0757	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	14 (77.8)	13 (68.4)
	95% CI	(58.6, 97.0)	(47.5, 89.3)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1368	
	95% CI	(0.7675, 1.6837)	
	Two-sided P-value	0.5225	
	P-value of interaction	0.3963	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	216	220
	Week 26, N	216	220
	Number of Subjects with observed Case, N1 (%)	176 (81.5)	194 (88.2)
	Number of Subjects with NRI, N2 (%)	40 (18.5)	26 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	155 (71.8)	174 (79.1)
	95% CI	(65.8, 77.8)	(73.7, 84.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9073	
	95% CI	(0.8146, 1.0105)	
	Two-sided P-value	0.0769	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Baseline, N	146	145
	Week 26, N	146	145
	Number of Subjects with observed Case, N1 (%)	124 (84.9)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	22 (15.1)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	118 (80.8)	120 (82.8)
	95% CI	(74.4, 87.2)	(76.6, 88.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9766	
	95% CI	(0.8762, 1.0885)	
	Two-sided P-value	0.6687	
	P-value of interaction	0.3454	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Exposed	Baseline, N	40	51
	Week 26, N	40	51
	Number of Subjects with observed Case, N1 (%)	32 (80.0)	44 (86.3)
	Number of Subjects with NRI, N2 (%)	8 (20.0)	7 (13.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	25 (62.5)	40 (78.4)
	95% CI	(47.5, 77.5)	(67.1, 89.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.7969	
	95% CI	(0.6023, 1.0542)	
	Two-sided P-value	0.1118	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Previous cyclosporine exposure

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Previous cyclosporine exposure: Cyclosporine Naive	Baseline, N	322	314
	Week 26, N	322	314
	Number of Subjects with observed Case, N1 (%)	268 (83.2)	279 (88.9)
	Number of Subjects with NRI, N2 (%)	54 (16.8)	35 (11.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	248 (77.0)	254 (80.9)
	95% CI	(72.4, 81.6)	(76.5, 85.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9521	
	95% CI	(0.8786, 1.0317)	
	Two-sided P-value	0.2311	
	P-value of interaction	0.2309	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): <70	Baseline, N	132	136
	Week 26, N	132	136
	Number of Subjects with observed Case, N1 (%)	105 (79.5)	121 (89.0)
	Number of Subjects with NRI, N2 (%)	27 (20.5)	15 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	96 (72.7)	111 (81.6)
	95% CI	(65.1, 80.3)	(75.1, 88.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8911	
	95% CI	(0.7813, 1.0162)	
	Two-sided P-value	0.0855	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >=70 and <=100	Baseline, N	196	184
	Week 26, N	196	184
	Number of Subjects with observed Case, N1 (%)	168 (85.7)	166 (90.2)
	Number of Subjects with NRI, N2 (%)	28 (14.3)	18 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	151 (77.0)	149 (81.0)
	95% CI	(71.2, 82.9)	(75.3, 86.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9514	
	95% CI	(0.8577, 1.0553)	
	Two-sided P-value	0.3459	
Weight (kg): >100	Baseline, N	34	45
	Week 26, N	34	45
	Number of Subjects with observed Case, N1 (%)	27 (79.4)	36 (80.0)
	Number of Subjects with NRI, N2 (%)	7 (20.6)	9 (20.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Weight

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Weight (kg): >100	Responders, n (%)	26 (76.5)	34 (75.6)
	95% CI	(62.2, 90.7)	(63.0, 88.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0121	
	95% CI	(0.7884, 1.2993)	
	Two-sided P-value	0.9247	
	P-value of interaction	0.6038	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: <26	Baseline, N	222	220
	Week 26, N	222	220
	Number of Subjects with observed Case, N1 (%)	184 (82.9)	194 (88.2)
	Number of Subjects with NRI, N2 (%)	38 (17.1)	26 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	165 (74.3)	175 (79.5)
	95% CI	(68.6, 80.1)	(74.2, 84.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9344	
	95% CI	(0.8435, 1.0350)	
	Two-sided P-value	0.1934	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

AD Duration

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
AD Duration (years) group: >=26	Baseline, N	140	145
	Week 26, N	140	145
	Number of Subjects with observed Case, N1 (%)	116 (82.9)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	24 (17.1)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	108 (77.1)	119 (82.1)
	95% CI	(70.2, 84.1)	(75.8, 88.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9400	
	95% CI	(0.8354, 1.0577)	
	Two-sided P-value	0.3038	
	P-value of interaction	0.9401	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: 16-25	Baseline, N	181	183
	Week 26, N	181	183
	Number of Subjects with observed Case, N1 (%)	144 (79.6)	160 (87.4)
	Number of Subjects with NRI, N2 (%)	37 (20.4)	23 (12.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	127 (70.2)	142 (77.6)
	95% CI	(63.5, 76.8)	(71.6, 83.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9042	
	95% CI	(0.7997, 1.0224)	
	Two-sided P-value	0.1082	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline EASI group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline EASI group: >25	Baseline, N	172	174
	Week 26, N	172	174
	Number of Subjects with observed Case, N1 (%)	149 (86.6)	156 (89.7)
	Number of Subjects with NRI, N2 (%)	23 (13.4)	18 (10.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	140 (81.4)	145 (83.3)
	95% CI	(75.6, 87.2)	(77.8, 88.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9767	
	95% CI	(0.8859, 1.0769)	
	Two-sided P-value	0.6365	
	P-value of interaction	0.3352	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: 10-30	Baseline, N	122	133
	Week 26, N	122	133
	Number of Subjects with observed Case, N1 (%)	98 (80.3)	120 (90.2)
	Number of Subjects with NRI, N2 (%)	24 (19.7)	13 (9.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	86 (70.5)	110 (82.7)
	95% CI	(62.4, 78.6)	(76.3, 89.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8523	
	95% CI	(0.7420, 0.9791)	
	Two-sided P-value	0.0239	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >30-50	Baseline, N	132	121
	Week 26, N	132	121
	Number of Subjects with observed Case, N1 (%)	111 (84.1)	106 (87.6)
	Number of Subjects with NRI, N2 (%)	21 (15.9)	15 (12.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	102 (77.3)	94 (77.7)
	95% CI	(70.1, 84.4)	(70.3, 85.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9947	
	95% CI	(0.8708, 1.1361)	
	Two-sided P-value	0.9373	
Baseline % BSA group: >50	Baseline, N	108	111
	Week 26, N	108	111
	Number of Subjects with observed Case, N1 (%)	91 (84.3)	97 (87.4)
	Number of Subjects with NRI, N2 (%)	17 (15.7)	14 (12.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline % BSA group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline % BSA group: >50	Responders, n (%)	85 (78.7)	90 (81.1)
	95% CI	(71.0, 86.4)	(73.8, 88.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9707	
	95% CI	(0.8498, 1.1088)	
	Two-sided P-value	0.6611	
	P-value of interaction	0.2423	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Systemic Agents	Baseline, N	172	176
	Week 26, N	172	176
	Number of Subjects with observed Case, N1 (%)	140 (81.4)	160 (90.9)
	Number of Subjects with NRI, N2 (%)	32 (18.6)	16 (9.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	124 (72.1)	145 (82.4)
	95% CI	(65.4, 78.8)	(76.8, 88.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8751	
	95% CI	(0.7797, 0.9821)	
	Two-sided P-value	0.0234	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Prior AD medications

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Prior AD medications: Topical Agents Only	Baseline, N	188	189
	Week 26, N	188	189
	Number of Subjects with observed Case, N1 (%)	158 (84.0)	163 (86.2)
	Number of Subjects with NRI, N2 (%)	30 (16.0)	26 (13.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	147 (78.2)	149 (78.8)
	95% CI	(72.3, 84.1)	(73.0, 84.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9918	
	95% CI	(0.8924, 1.1023)	
	Two-sided P-value	0.8789	
	P-value of interaction	0.1165	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: 4-6	Baseline, N	83	105
	Week 26, N	83	105
	Number of Subjects with observed Case, N1 (%)	73 (88.0)	94 (89.5)
	Number of Subjects with NRI, N2 (%)	10 (12.0)	11 (10.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	64 (77.1)	88 (83.8)
	95% CI	(68.1, 86.1)	(76.8, 90.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9200	
	95% CI	(0.7965, 1.0628)	
	Two-sided P-value	0.2575	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD (VAS) of Pruritus >= 2 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 2, Main Analysis)
(Protocol B7451050)

Baseline PP-NRS group

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline PP-NRS group: >=7	Baseline, N	274	259
	Week 26, N	274	259
	Number of Subjects with observed Case, N1 (%)	225 (82.1)	228 (88.0)
	Number of Subjects with NRI, N2 (%)	49 (17.9)	31 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	207 (75.5)	206 (79.5)
	95% CI	(70.5, 80.6)	(74.6, 84.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9498	
	95% CI	(0.8669, 1.0408)	
	Two-sided P-value	0.2698	
	P-value of interaction	0.7145	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; VAS = visual analogue scale; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Table 14.3.1.5.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

			Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**			
Overall	Overall	N	362	365
		n (%)	264 (72.9)	237 (64.9)
		95% CI[a]	(68.35, 77.51)	(60.04, 69.83)
		Relative Risk (95% CI)[a]	1.12 (1.02, 1.24)	
		P-value	0.0203	
		Odds Ratio (95% CI)[a]	1.45 (1.06, 2.00)	
		P-value	0.0201	
		Risk Difference% (95% CI)[a]	8.00 (1.29, 14.70)	
		P-value	0.0194	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR or OR can't be calculated.
a. Results calculated with normal approximation.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 23SEP2021 (23:43)
Output File: ./nda1_cdisc/B7451050_GBA/adae_prop_2_e

Table 14.3.1.5.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

			Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**			
Overall	Overall	N	362	365
		n (%)	6 (1.7)	5 (1.4)
		95% CI[a]	(0.34, 2.97)	(0.18, 2.56)
		Relative Risk (95% CI)[a]	1.21 (0.37, 3.93)	
		P-value	0.7512	
		Odds Ratio (95% CI)[a]	1.21 (0.37, 4.01)	
		P-value	0.7511	
		Risk Difference% (95% CI)[a]	0.29 (-1.49, 2.06)	
		P-value	0.7509	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR or OR can't be calculated.
a. Results calculated with normal approximation.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 23SEP2021 (23:43)
Output File: ./nda1_cdisc/B7451050_GBA/adae_prop_5_e

Table 14.3.1.5.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

			Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**			
Overall	Overall	N	362	365
		n (%)	10 (2.8)	8 (2.2)
		95% CI[a]	(1.07, 4.45)	(0.69, 3.69)
		Relative Risk (95% CI)[a]	1.26 (0.50, 3.16)	
		P-value	0.6214	
		Odds Ratio (95% CI)[a]	1.27 (0.49, 3.25)	
		P-value	0.6213	
		Risk Difference% (95% CI)[a]	0.57 (-1.69, 2.83)	
		P-value	0.6206	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR or OR can't be calculated.
a. Results calculated with normal approximation.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 23SEP2021 (23:43)
Output File: ./nda1_cdisc/B7451050_GBA/adae_prop_6_e

Table 14.3.1.5.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events (All Causalities) - Safety Analysis Set
(Protocol B7451050)

			Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**			
Overall	Overall	N	362	365
		n (%)	267 (73.8)	237 (64.9)
		95% CI[a]	(69.22, 78.29)	(60.04, 69.83)
		Relative Risk (95% CI)[a]	1.14 (1.03, 1.25)	
		P-value	0.0102	
		Odds Ratio (95% CI)[a]	1.52 (1.10, 2.09)	
		P-value	0.0101	
		Risk Difference% (95% CI)[a]	8.83 (2.15, 15.50)	
		P-value	0.0095	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR or OR can't be calculated.
a. Results calculated with normal approximation.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 23SEP2021 (23:43)
Output File: ./nda1_cdisc/B7451050_GBA/adae_prop_10

Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	174 (75.7)	162 (65.6)
			95% CI[a]	(70.11, 81.20)	(59.66, 71.51)
			Relative Risk (95% CI)[a]	1.15 (1.03, 1.30)	
			P-value	0.0162	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	94 (71.2)	77 (65.3)
			95% CI[a]	(63.49, 78.94)	(56.66, 73.85)
			Relative Risk (95% CI)[a]	1.09 (0.92, 1.29)	
			P-value	0.3154	
			Test for interaction[b]	0.5042	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:29)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_1

Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	251 (73.6)	236 (66.7)
			95% CI[a]	(68.93, 78.29)	(61.76, 71.58)
			Relative Risk (95% CI)[a]	1.10 (1.00, 1.22)	
			P-value	0.0460	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	17 (81.0)	3 (27.3)
			95% CI[a]	(64.16, 97.75)	(0.95, 53.59)
			Relative Risk (95% CI)[a]	2.97 (1.11, 7.96)	
			P-value	0.0307	
			Test for interaction[b]	0.0270	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	141 (73.1)	128 (62.7)
			95% CI[a]	(66.80, 79.32)	(56.11, 69.38)
			Relative Risk (95% CI)[a]	1.16 (1.02, 1.33)	
			P-value	0.0284	
Sex: Female	Overall	Overall	N	169	161
			n (%)	127 (75.1)	111 (68.9)
			95% CI[a]	(68.63, 81.66)	(61.80, 76.09)
			Relative Risk (95% CI)[a]	1.09 (0.95, 1.25)	
			P-value	0.2115	
			Test for interaction[b]	0.6631	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	201 (74.7)	168 (67.7)
			95% CI[a]	(69.53, 79.91)	(61.92, 73.56)
			Relative Risk (95% CI)[a]	1.10 (0.99, 1.23)	
			P-value	0.0819	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	16 (64.0)	13 (50.0)
			95% CI[a]	(45.18, 82.82)	(30.78, 69.22)
			Relative Risk (95% CI)[a]	1.28 (0.79, 2.08)	
			P-value	0.3174	
Race: Asian	Overall	Overall	N	62	83
			n (%)	45 (72.6)	53 (63.9)
			95% CI[a]	(61.48, 83.68)	(53.52, 74.19)
			Relative Risk (95% CI)[a]	1.14 (0.91, 1.42)	
			P-value	0.2597	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: Other	Overall	Overall	N	6	8
			n (%)	6 (100.0)	5 (62.5)
			95% CI[a]	(54.07, 100.00)	(28.95, 96.05)
			Relative Risk (95% CI)[a]	1.48 (0.83, 2.64)	
			P-value	0.1882	
			Test for interaction[b]	0.8236	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	133 (75.1)	130 (66.7)
			95% CI[a]	(68.77, 81.51)	(60.05, 73.28)
			Relative Risk (95% CI)[a]	1.13 (0.99, 1.28)	
			P-value	0.0723	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	111 (74.0)	90 (68.2)
			95% CI[a]	(66.98, 81.02)	(60.24, 76.13)
			Relative Risk (95% CI)[a]	1.09 (0.93, 1.26)	
			P-value	0.2855	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	12 (70.6)	10 (52.6)
			95% CI[a]	(48.93, 92.25)	(30.18, 75.08)
			Relative Risk (95% CI)[a]	1.34 (0.79, 2.27)	
			P-value	0.2736	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	12 (66.7)	9 (47.4)
			95% CI[a]	(44.89, 88.44)	(24.92, 69.82)
			Relative Risk (95% CI)[a]	1.41 (0.79, 2.50)	
			P-value	0.2446	
			Test for interaction[b]	0.9036	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	162 (75.0)	148 (67.3)
			95% CI[a]	(69.23, 80.77)	(61.07, 73.47)
			Relative Risk (95% CI)[a]	1.11 (0.99, 1.26)	
			P-value	0.0760	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	106 (72.6)	91 (62.8)
			95% CI[a]	(65.37, 79.84)	(54.89, 70.63)
			Relative Risk (95% CI)[a]	1.16 (0.99, 1.36)	
			P-value	0.0746	
			Test for interaction[b]	0.8701	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	31 (77.5)	29 (56.9)
			95% CI[a]	(64.56, 90.44)	(43.27, 70.46)
			Relative Risk (95% CI)[a]	1.36 (1.02, 1.82)	
			P-value	0.0374	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	237 (73.6)	210 (66.9)
			95% CI[a]	(68.79, 78.42)	(61.67, 72.08)
			Relative Risk (95% CI)[a]	1.10 (0.99, 1.22)	
			P-value	0.0648	
			Test for interaction[b]	0.2343	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	99 (75.0)	91 (66.9)
			95% CI[a]	(67.61, 82.39)	(59.00, 74.82)
			Relative Risk (95% CI)[a]	1.12 (0.96, 1.31)	
			P-value	0.1460	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	143 (73.0)	116 (63.0)
			95% CI[a]	(66.74, 79.18)	(56.07, 70.02)
			Relative Risk (95% CI)[a]	1.16 (1.01, 1.33)	
			P-value	0.0404	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	26 (76.5)	32 (71.1)
			95% CI[a]	(62.21, 90.73)	(57.87, 84.35)
			Relative Risk (95% CI)[a]	1.08 (0.83, 1.40)	
			P-value	0.5889	
			Test for interaction[b]	0.9647	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	159 (71.6)	133 (60.5)
			95% CI[a]	(65.69, 77.55)	(53.99, 66.92)
			Relative Risk (95% CI)[a]	1.18 (1.03, 1.36)	
			P-value	0.0140	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	109 (77.9)	106 (73.1)
			95% CI[a]	(70.98, 84.73)	(65.89, 80.32)
			Relative Risk (95% CI)[a]	1.07 (0.93, 1.22)	
			P-value	0.3513	
			Test for interaction[b]	0.5818	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	138 (76.2)	128 (69.9)
			95% CI[a]	(70.04, 82.44)	(63.30, 76.59)
			Relative Risk (95% CI)[a]	1.09 (0.96, 1.24)	
			P-value	0.1766	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	122 (70.9)	104 (59.8)
			95% CI[a]	(64.14, 77.72)	(52.48, 67.06)
			Relative Risk (95% CI)[a]	1.19 (1.02, 1.39)	
			P-value	0.0304	
			Test for interaction[b]	0.6971	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	89 (73.0)	92 (69.2)
			95% CI[a]	(65.07, 80.83)	(61.32, 77.02)
			Relative Risk (95% CI)[a]	1.05 (0.90, 1.23)	
			P-value	0.5059	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	97 (73.5)	80 (66.1)
			95% CI[a]	(65.95, 81.02)	(57.68, 74.55)
			Relative Risk (95% CI)[a]	1.11 (0.94, 1.31)	
			P-value	0.2056	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	82 (75.9)	67 (60.4)
			95% CI[a]	(67.86, 83.99)	(51.26, 69.46)
			Relative Risk (95% CI)[a]	1.26 (1.05, 1.51)	
			P-value	0.0147	
			Test for interaction[b]	0.4238	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	132 (76.7)	118 (67.0)
			95% CI[a]	(70.43, 83.06)	(60.10, 73.99)
			Relative Risk (95% CI)[a]	1.14 (1.00, 1.31)	
			P-value	0.0453	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	135 (71.8)	121 (64.0)
			95% CI[a]	(65.38, 78.24)	(57.18, 70.86)
			Relative Risk (95% CI)[a]	1.12 (0.98, 1.29)	
			P-value	0.1066	
			Test for interaction[b]	0.6515	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	64 (77.1)	72 (68.6)
			95% CI[a]	(68.07, 86.15)	(59.69, 77.45)
			Relative Risk (95% CI)[a]	1.12 (0.94, 1.34)	
			P-value	0.1880	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	201 (73.4)	166 (64.1)
			95% CI[a]	(68.12, 78.59)	(58.25, 69.94)
			Relative Risk (95% CI)[a]	1.14 (1.02, 1.29)	
			P-value	0.0223	
			Test for interaction[b]	0.9473	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	170 (73.9)	161 (65.2)
			95% CI[a]	(68.24, 79.59)	(59.24, 71.12)
			Relative Risk (95% CI)[a]	1.13 (1.01, 1.28)	
			P-value	0.0387	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	94 (71.2)	76 (64.4)
			95% CI[a]	(63.49, 78.94)	(55.77, 73.05)
			Relative Risk (95% CI)[a]	1.11 (0.93, 1.31)	
			P-value	0.2538	
			Test for interaction[b]	0.7420	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_e

Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	247 (72.4)	234 (66.1)
			95% CI[a]	(67.69, 77.18)	(61.17, 71.03)
			Relative Risk (95% CI)[a]	1.10 (0.99, 1.21)	
			P-value	0.0709	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	17 (81.0)	3 (27.3)
			95% CI[a]	(64.16, 97.75)	(0.95, 53.59)
			Relative Risk (95% CI)[a]	2.97 (1.11, 7.96)	
			P-value	0.0307	
			Test for interaction[b]	0.0234	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	138 (71.5)	126 (61.8)
			95% CI[a]	(65.13, 77.87)	(55.10, 68.43)
			Relative Risk (95% CI)[a]	1.16 (1.01, 1.33)	
			P-value	0.0404	
Sex: Female	Overall	Overall	N	169	161
			n (%)	126 (74.6)	111 (68.9)
			95% CI[a]	(67.99, 81.12)	(61.80, 76.09)
			Relative Risk (95% CI)[a]	1.08 (0.94, 1.24)	
			P-value	0.2595	
			Test for interaction[b]	0.6783	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_e

Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	200 (74.3)	167 (67.3)
			95% CI[a]	(69.13, 79.57)	(61.50, 73.18)
			Relative Risk (95% CI)[a]	1.10 (0.99, 1.23)	
			P-value	0.0818	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	16 (64.0)	13 (50.0)
			95% CI[a]	(45.18, 82.82)	(30.78, 69.22)
			Relative Risk (95% CI)[a]	1.28 (0.79, 2.08)	
			P-value	0.3174	
Race: Asian	Overall	Overall	N	62	83
			n (%)	43 (69.4)	52 (62.7)
			95% CI[a]	(57.88, 80.83)	(52.24, 73.06)
			Relative Risk (95% CI)[a]	1.11 (0.88, 1.40)	
			P-value	0.3954	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_e

Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: Other	Overall	Overall	N	6	8
			n (%)	5 (83.3)	5 (62.5)
			95% CI[a]	(53.51, 100.00)	(28.95, 96.05)
			Relative Risk (95% CI)[a]	1.33 (0.70, 2.54)	
			P-value	0.3821	
			Test for interaction[b]	0.9382	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	132 (74.6)	129 (66.2)
			95% CI[a]	(68.16, 80.99)	(59.51, 72.80)
			Relative Risk (95% CI)[a]	1.13 (0.99, 1.29)	
			P-value	0.0756	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	109 (72.7)	89 (67.4)
			95% CI[a]	(65.53, 79.80)	(59.43, 75.42)
			Relative Risk (95% CI)[a]	1.08 (0.92, 1.26)	
			P-value	0.3404	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	11 (64.7)	10 (52.6)
			95% CI[a]	(41.99, 87.42)	(30.18, 75.08)
			Relative Risk (95% CI)[a]	1.23 (0.71, 2.14)	
			P-value	0.4637	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_e

Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	12 (66.7)	9 (47.4)
			95% CI[a]	(44.89, 88.44)	(24.92, 69.82)
			Relative Risk (95% CI)[a]	1.41 (0.79, 2.50)	
			P-value	0.2446	
			Test for interaction[b]	0.9209	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	161 (74.5)	147 (66.8)
			95% CI[a]	(68.73, 80.35)	(60.60, 73.04)
			Relative Risk (95% CI)[a]	1.12 (0.99, 1.26)	
			P-value	0.0777	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	103 (70.5)	90 (62.1)
			95% CI[a]	(63.15, 77.94)	(54.17, 69.97)
			Relative Risk (95% CI)[a]	1.14 (0.96, 1.34)	
			P-value	0.1279	
			Test for interaction[b]	0.9582	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_e

Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	29 (72.5)	29 (56.9)
			95% CI[a]	(58.66, 86.34)	(43.27, 70.46)
			Relative Risk (95% CI)[a]	1.28 (0.94, 1.73)	
			P-value	0.1196	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	235 (73.0)	208 (66.2)
			95% CI[a]	(68.13, 77.83)	(61.01, 71.47)
			Relative Risk (95% CI)[a]	1.10 (0.99, 1.22)	
			P-value	0.0658	
			Test for interaction[b]	0.4855	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	97 (73.5)	90 (66.2)
			95% CI[a]	(65.95, 81.02)	(58.23, 74.13)
			Relative Risk (95% CI)[a]	1.11 (0.95, 1.30)	
			P-value	0.1936	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	141 (71.9)	115 (62.5)
			95% CI[a]	(65.65, 78.23)	(55.50, 69.50)
			Relative Risk (95% CI)[a]	1.15 (1.00, 1.33)	
			P-value	0.0523	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	26 (76.5)	32 (71.1)
			95% CI[a]	(62.21, 90.73)	(57.87, 84.35)
			Relative Risk (95% CI)[a]	1.08 (0.83, 1.40)	
			P-value	0.5889	
			Test for interaction[b]	0.9681	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	157 (70.7)	133 (60.5)
			95% CI[a]	(64.73, 76.71)	(53.99, 66.92)
			Relative Risk (95% CI)[a]	1.17 (1.02, 1.34)	
			P-value	0.0241	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	107 (76.4)	104 (71.7)
			95% CI[a]	(69.40, 83.46)	(64.39, 79.05)
			Relative Risk (95% CI)[a]	1.07 (0.93, 1.22)	
			P-value	0.3652	
			Test for interaction[b]	0.6238	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	136 (75.1)	128 (69.9)
			95% CI[a]	(68.84, 81.43)	(63.30, 76.59)
			Relative Risk (95% CI)[a]	1.07 (0.95, 1.22)	
			P-value	0.2678	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	120 (69.8)	102 (58.6)
			95% CI[a]	(62.90, 76.63)	(51.30, 65.94)
			Relative Risk (95% CI)[a]	1.19 (1.02, 1.40)	
			P-value	0.0318	
			Test for interaction[b]	0.5823	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.1.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	87 (71.3)	92 (69.2)
			95% CI[a]	(63.29, 79.34)	(61.32, 77.02)
			Relative Risk (95% CI)[a]	1.03 (0.88, 1.21)	
			P-value	0.7088	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	96 (72.7)	80 (66.1)
			95% CI[a]	(65.13, 80.32)	(57.68, 74.55)
			Relative Risk (95% CI)[a]	1.10 (0.93, 1.30)	
			P-value	0.2572	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	81 (75.0)	65 (58.6)
			95% CI[a]	(66.83, 83.17)	(49.39, 67.72)
			Relative Risk (95% CI)[a]	1.28 (1.06, 1.55)	
			P-value	0.0110	
			Test for interaction[b]	0.2884	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_e

Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	129 (75.0)	117 (66.5)
			95% CI[a]	(68.53, 81.47)	(59.50, 73.45)
			Relative Risk (95% CI)[a]	1.13 (0.98, 1.29)	
			P-value	0.0818	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	134 (71.3)	120 (63.5)
			95% CI[a]	(64.81, 77.74)	(56.63, 70.36)
			Relative Risk (95% CI)[a]	1.12 (0.97, 1.29)	
			P-value	0.1083	
			Test for interaction[b]	0.8128	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	64 (77.1)	71 (67.6)
			95% CI[a]	(68.07, 86.15)	(58.67, 76.57)
			Relative Risk (95% CI)[a]	1.14 (0.96, 1.36)	
			P-value	0.1455	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	197 (71.9)	165 (63.7)
			95% CI[a]	(66.58, 77.22)	(57.85, 69.56)
			Relative Risk (95% CI)[a]	1.13 (1.00, 1.27)	
			P-value	0.0446	
			Test for interaction[b]	0.7423	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	3 (1.3)	4 (1.6)
			95% CI[a]	(0.00, 2.77)	(0.05, 3.19)
			Relative Risk (95% CI)[a]	0.81 (0.18, 3.56)	
			P-value	0.7754	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	3 (2.3)	2 (1.7)
			95% CI[a]	(0.00, 4.82)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	1.34 (0.23, 7.89)	
			P-value	0.7456	
			Test for interaction[b]	0.6669	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	5 (1.5)	6 (1.7)
			95% CI[a]	(0.19, 2.74)	(0.35, 3.04)
			Relative Risk (95% CI)[a]	0.87 (0.27, 2.81)	
			P-value	0.8094	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.9338	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5

Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	4 (2.1)	4 (2.0)
			95% CI[a]	(0.06, 4.08)	(0.06, 3.86)
			Relative Risk (95% CI)[a]	1.06 (0.27, 4.17)	
			P-value	0.9369	
Sex: Female	Overall	Overall	N	169	161
			n (%)	2 (1.2)	2 (1.2)
			95% CI[a]	(0.00, 2.81)	(0.00, 2.95)
			Relative Risk (95% CI)[a]	0.95 (0.14, 6.68)	
			P-value	0.9611	
			Test for interaction[b]	0.9268	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5

Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	6 (2.2)	5 (2.0)
			95% CI[a]	(0.47, 4.00)	(0.27, 3.77)
			Relative Risk (95% CI)[a]	1.11 (0.34, 3.58)	
			P-value	0.8661	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	0	0
Race: Asian	Overall	Overall	N	62	83
			n (%)	0	1 (1.2)
			95% CI[a]	(0.00, 5.78)	(0.00, 3.55)
			Relative Risk (95% CI)[a]	0.66 (0.02, 19.48)	
			P-value	0.8123	
Race: Other	Overall	Overall	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.9908	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	2 (1.1)	3 (1.5)
			95% CI[a]	(0.00, 2.69)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	0.73 (0.12, 4.34)	
			P-value	0.7336	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	4 (2.7)	3 (2.3)
			95% CI[a]	(0.09, 5.24)	(0.00, 4.82)
			Relative Risk (95% CI)[a]	1.17 (0.27, 5.15)	
			P-value	0.8322	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	0	0
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9862	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5

Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	5 (2.3)	5 (2.3)
			95% CI[a]	(0.31, 4.32)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	1.02 (0.30, 3.47)	
			P-value	0.9766	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	1 (0.7)	1 (0.7)
			95% CI[a]	(0.00, 2.02)	(0.00, 2.04)
			Relative Risk (95% CI)[a]	0.99 (0.06, 15.73)	
			P-value	0.9961	
			Test for interaction[b]	0.9783	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5

Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	1 (2.5)	1 (2.0)
			95% CI[a]	(0.00, 7.34)	(0.00, 5.77)
			Relative Risk (95% CI)[a]	1.27 (0.08, 19.76)	
			P-value	0.8621	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	5 (1.6)	5 (1.6)
			95% CI[a]	(0.20, 2.90)	(0.21, 2.98)
			Relative Risk (95% CI)[a]	0.98 (0.29, 3.34)	
			P-value	0.9680	
			Test for interaction[b]	0.8605	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	3 (2.3)	2 (1.5)
			95% CI[a]	(0.00, 4.82)	(0.00, 3.49)
			Relative Risk (95% CI)[a]	1.55 (0.26, 9.10)	
			P-value	0.6304	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	3 (1.5)	3 (1.6)
			95% CI[a]	(0.00, 3.25)	(0.00, 3.46)
			Relative Risk (95% CI)[a]	0.94 (0.19, 4.59)	
			P-value	0.9378	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	0	1 (2.2)
			95% CI[a]	(0.00, 10.28)	(0.00, 6.53)
			Relative Risk (95% CI)[a]	0.65 (0.02, 18.88)	
			P-value	0.8034	
			Test for interaction[b]	0.8662	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	5 (2.3)	4 (1.8)
			95% CI[a]	(0.30, 4.20)	(0.05, 3.58)
			Relative Risk (95% CI)[a]	1.24 (0.34, 4.55)	
			P-value	0.7471	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	1 (0.7)	2 (1.4)
			95% CI[a]	(0.00, 2.11)	(0.00, 3.28)
			Relative Risk (95% CI)[a]	0.52 (0.05, 5.65)	
			P-value	0.5893	
			Test for interaction[b]	0.5428	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5

Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	6 (3.3)	5 (2.7)
			95% CI[a]	(0.71, 5.92)	(0.37, 5.09)
			Relative Risk (95% CI)[a]	1.21 (0.38, 3.90)	
			P-value	0.7458	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	0	1 (0.6)
			95% CI[a]	(0.00, 2.12)	(0.00, 1.70)
			Relative Risk (95% CI)[a]	0.50 (0.02, 14.94)	
			P-value	0.6921	
			Test for interaction[b]	0.6546	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	5 (4.1)	3 (2.3)
			95% CI[a]	(0.58, 7.62)	(0.00, 4.78)
			Relative Risk (95% CI)[a]	1.82 (0.44, 7.44)	
			P-value	0.4065	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	1 (0.8)	3 (2.5)
			95% CI[a]	(0.00, 2.24)	(0.00, 5.25)
			Relative Risk (95% CI)[a]	0.31 (0.03, 2.90)	
			P-value	0.3016	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	0	0
			Test for interaction[b]	0.4082	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	4 (2.3)	1 (0.6)
			95% CI[a]	(0.07, 4.58)	(0.00, 1.68)
			Relative Risk (95% CI)[a]	4.09 (0.46, 36.25)	
			P-value	0.2054	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	2 (1.1)	5 (2.6)
			95% CI[a]	(0.00, 2.53)	(0.36, 4.93)
			Relative Risk (95% CI)[a]	0.40 (0.08, 2.05)	
			P-value	0.2726	
			Test for interaction[b]	0.0783	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.2 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	2 (2.4)	3 (2.9)
			95% CI[a]	(0.00, 5.71)	(0.00, 6.04)
			Relative Risk (95% CI)[a]	0.84 (0.14, 4.93)	
			P-value	0.8500	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	4 (1.5)	3 (1.2)
			95% CI[a]	(0.04, 2.88)	(0.00, 2.46)
			Relative Risk (95% CI)[a]	1.26 (0.28, 5.58)	
			P-value	0.7604	
			Test for interaction[b]	0.7687	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5

Table 14.3.1.6.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	3 (1.3)	4 (1.6)
			95% CI[a]	(0.00, 2.77)	(0.05, 3.19)
			Relative Risk (95% CI)[a]	0.81 (0.18, 3.56)	
			P-value	0.7754	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	3 (2.3)	1 (0.8)
			95% CI[a]	(0.00, 4.82)	(0.00, 2.50)
			Relative Risk (95% CI)[a]	2.68 (0.28, 25.43)	
			P-value	0.3901	
			Test for interaction[b]	0.3599	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	5 (1.5)	5 (1.4)
			95% CI[a]	(0.19, 2.74)	(0.18, 2.64)
			Relative Risk (95% CI)[a]	1.04 (0.30, 3.55)	
			P-value	0.9525	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.9622	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	4 (2.1)	3 (1.5)
			95% CI[a]	(0.06, 4.08)	(0.00, 3.12)
			Relative Risk (95% CI)[a]	1.41 (0.32, 6.22)	
			P-value	0.6504	
Sex: Female	Overall	Overall	N	169	161
			n (%)	2 (1.2)	2 (1.2)
			95% CI[a]	(0.00, 2.81)	(0.00, 2.95)
			Relative Risk (95% CI)[a]	0.95 (0.14, 6.68)	
			P-value	0.9611	
			Test for interaction[b]	0.7121	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5_e

Table 14.3.1.6.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	6 (2.2)	4 (1.6)
			95% CI[a]	(0.47, 4.00)	(0.05, 3.18)
			Relative Risk (95% CI)[a]	1.38 (0.39, 4.84)	
			P-value	0.6122	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	0	0
Race: Asian	Overall	Overall	N	62	83
			n (%)	0	1 (1.2)
			95% CI[a]	(0.00, 5.78)	(0.00, 3.55)
			Relative Risk (95% CI)[a]	0.66 (0.02, 19.48)	
			P-value	0.8123	
Race: Other	Overall	Overall	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.9658	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5_e

Table 14.3.1.6.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	2 (1.1)	3 (1.5)
			95% CI[a]	(0.00, 2.69)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	0.73 (0.12, 4.34)	
			P-value	0.7336	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	4 (2.7)	2 (1.5)
			95% CI[a]	(0.09, 5.24)	(0.00, 3.60)
			Relative Risk (95% CI)[a]	1.76 (0.33, 9.45)	
			P-value	0.5099	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	0	0
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9031	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5_e

Table 14.3.1.6.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	5 (2.3)	5 (2.3)
			95% CI[a]	(0.31, 4.32)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	1.02 (0.30, 3.47)	
			P-value	0.9766	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	1 (0.7)	0
			95% CI[a]	(0.00, 2.02)	(0.00, 2.51)
			Relative Risk (95% CI)[a]	1.99 (0.07, 58.95)	
			P-value	0.6898	
			Test for interaction[b]	0.8593	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5_e

Table 14.3.1.6.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	1 (2.5)	1 (2.0)
			95% CI[a]	(0.00, 7.34)	(0.00, 5.77)
			Relative Risk (95% CI)[a]	1.27 (0.08, 19.76)	
			P-value	0.8621	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	5 (1.6)	4 (1.3)
			95% CI[a]	(0.20, 2.90)	(0.03, 2.51)
			Relative Risk (95% CI)[a]	1.22 (0.33, 4.50)	
			P-value	0.7663	
			Test for interaction[b]	0.9361	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5_e

Table 14.3.1.6.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	3 (2.3)	2 (1.5)
			95% CI[a]	(0.00, 4.82)	(0.00, 3.49)
			Relative Risk (95% CI)[a]	1.55 (0.26, 9.10)	
			P-value	0.6304	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	3 (1.5)	2 (1.1)
			95% CI[a]	(0.00, 3.25)	(0.00, 2.59)
			Relative Risk (95% CI)[a]	1.41 (0.24, 8.33)	
			P-value	0.7059	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	0	1 (2.2)
			95% CI[a]	(0.00, 10.28)	(0.00, 6.53)
			Relative Risk (95% CI)[a]	0.65 (0.02, 18.88)	
			P-value	0.8034	
			Test for interaction[b]	0.8996	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	5 (2.3)	4 (1.8)
			95% CI[a]	(0.30, 4.20)	(0.05, 3.58)
			Relative Risk (95% CI)[a]	1.24 (0.34, 4.55)	
			P-value	0.7471	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	1 (0.7)	1 (0.7)
			95% CI[a]	(0.00, 2.11)	(0.00, 2.04)
			Relative Risk (95% CI)[a]	1.04 (0.07, 16.40)	
			P-value	0.9801	
			Test for interaction[b]	0.8051	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5_e

Table 14.3.1.6.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	6 (3.3)	4 (2.2)
			95% CI[a]	(0.71, 5.92)	(0.07, 4.30)
			Relative Risk (95% CI)[a]	1.52 (0.44, 5.28)	
			P-value	0.5132	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	0	1 (0.6)
			95% CI[a]	(0.00, 2.12)	(0.00, 1.70)
			Relative Risk (95% CI)[a]	0.50 (0.02, 14.94)	
			P-value	0.6921	
			Test for interaction[b]	0.4466	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5_e

Table 14.3.1.6.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	5 (4.1)	2 (1.5)
			95% CI[a]	(0.58, 7.62)	(0.00, 3.57)
			Relative Risk (95% CI)[a]	2.73 (0.54, 13.79)	
			P-value	0.2255	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	1 (0.8)	3 (2.5)
			95% CI[a]	(0.00, 2.24)	(0.00, 5.25)
			Relative Risk (95% CI)[a]	0.31 (0.03, 2.90)	
			P-value	0.3016	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	0	0
			Test for interaction[b]	0.2627	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.2.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	4 (2.3)	1 (0.6)
			95% CI[a]	(0.07, 4.58)	(0.00, 1.68)
			Relative Risk (95% CI)[a]	4.09 (0.46, 36.25)	
			P-value	0.2054	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	2 (1.1)	4 (2.1)
			95% CI[a]	(0.00, 2.53)	(0.06, 4.17)
			Relative Risk (95% CI)[a]	0.50 (0.09, 2.71)	
			P-value	0.4238	
			Test for interaction[b]	0.1232	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	2 (2.4)	3 (2.9)
			95% CI[a]	(0.00, 5.71)	(0.00, 6.04)
			Relative Risk (95% CI)[a]	0.84 (0.14, 4.93)	
			P-value	0.8500	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	4 (1.5)	2 (0.8)
			95% CI[a]	(0.04, 2.88)	(0.00, 1.84)
			Relative Risk (95% CI)[a]	1.89 (0.35, 10.23)	
			P-value	0.4599	
			Test for interaction[b]	0.6534	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	6 (2.6)	6 (2.4)
			95% CI[a]	(0.55, 4.67)	(0.51, 4.35)
			Relative Risk (95% CI)[a]	1.07 (0.35, 3.28)	
			P-value	0.9004	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	5 (3.8)	2 (1.7)
			95% CI[a]	(0.53, 7.04)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	2.23 (0.44, 11.30)	
			P-value	0.3309	
			Test for interaction[b]	0.4442	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	10 (2.9)	8 (2.3)
			95% CI[a]	(1.14, 4.72)	(0.71, 3.81)
			Relative Risk (95% CI)[a]	1.30 (0.52, 3.25)	
			P-value	0.5779	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.9746	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	6 (3.1)	2 (1.0)
			95% CI[a]	(0.66, 5.56)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	3.17 (0.65, 15.52)	
			P-value	0.1544	
Sex: Female	Overall	Overall	N	169	161
			n (%)	5 (3.0)	6 (3.7)
			95% CI[a]	(0.40, 5.51)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	0.79 (0.25, 2.55)	
			P-value	0.6983	
			Test for interaction[b]	0.2392	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	9 (3.3)	6 (2.4)
			95% CI[a]	(1.20, 5.49)	(0.51, 4.33)
			Relative Risk (95% CI)[a]	1.38 (0.50, 3.83)	
			P-value	0.5327	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	1 (4.0)	0
			95% CI[a]	(0.00, 11.68)	(0.00, 13.23)
			Relative Risk (95% CI)[a]	2.12 (0.07, 60.46)	
			P-value	0.6603	
Race: Asian	Overall	Overall	N	62	83
			n (%)	1 (1.6)	2 (2.4)
			95% CI[a]	(0.00, 4.75)	(0.00, 5.71)
			Relative Risk (95% CI)[a]	0.67 (0.06, 7.22)	
			P-value	0.7407	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: Other	Overall	Overall	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.9140	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	5 (2.8)	6 (3.1)
			95% CI[a]	(0.38, 5.27)	(0.65, 5.50)
			Relative Risk (95% CI)[a]	0.92 (0.29, 2.96)	
			P-value	0.8861	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	5 (3.3)	2 (1.5)
			95% CI[a]	(0.46, 6.21)	(0.00, 3.60)
			Relative Risk (95% CI)[a]	2.20 (0.43, 11.15)	
			P-value	0.3410	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	1 (5.9)	0
			95% CI[a]	(0.00, 17.07)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.29 (0.08, 64.21)	
			P-value	0.6252	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.8432	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	5 (2.3)	5 (2.3)
			95% CI[a]	(0.31, 4.32)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	1.02 (0.30, 3.47)	
			P-value	0.9766	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	6 (4.1)	3 (2.1)
			95% CI[a]	(0.89, 7.33)	(0.00, 4.39)
			Relative Risk (95% CI)[a]	1.99 (0.51, 7.79)	
			P-value	0.3250	
			Test for interaction[b]	0.4201	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	2 (5.0)	2 (3.9)
			95% CI[a]	(0.00, 11.75)	(0.00, 9.25)
			Relative Risk (95% CI)[a]	1.28 (0.19, 8.66)	
			P-value	0.8037	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	9 (2.8)	6 (1.9)
			95% CI[a]	(0.99, 4.60)	(0.40, 3.43)
			Relative Risk (95% CI)[a]	1.46 (0.53, 4.06)	
			P-value	0.4655	
			Test for interaction[b]	0.9626	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	7 (5.3)	4 (2.9)
			95% CI[a]	(1.48, 9.13)	(0.10, 5.78)
			Relative Risk (95% CI)[a]	1.80 (0.54, 6.02)	
			P-value	0.3376	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	4 (2.0)	1 (0.5)
			95% CI[a]	(0.06, 4.02)	(0.00, 1.61)
			Relative Risk (95% CI)[a]	3.76 (0.42, 33.29)	
			P-value	0.2347	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	0	3 (6.7)
			95% CI[a]	(0.00, 10.28)	(0.00, 13.95)
			Relative Risk (95% CI)[a]	0.22 (0.01, 4.20)	
			P-value	0.3124	
			Test for interaction[b]	0.2866	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	6 (2.7)	5 (2.3)
			95% CI[a]	(0.57, 4.84)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	1.19 (0.37, 3.84)	
			P-value	0.7720	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	5 (3.6)	3 (2.1)
			95% CI[a]	(0.50, 6.65)	(0.00, 4.39)
			Relative Risk (95% CI)[a]	1.73 (0.42, 7.09)	
			P-value	0.4487	
			Test for interaction[b]	0.6625	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	6 (3.3)	4 (2.2)
			95% CI[a]	(0.71, 5.92)	(0.07, 4.30)
			Relative Risk (95% CI)[a]	1.52 (0.44, 5.28)	
			P-value	0.5132	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	5 (2.9)	4 (2.3)
			95% CI[a]	(0.40, 5.42)	(0.07, 4.53)
			Relative Risk (95% CI)[a]	1.26 (0.35, 4.63)	
			P-value	0.7230	
			Test for interaction[b]	0.8295	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	5 (4.1)	2 (1.5)
			95% CI[a]	(0.58, 7.62)	(0.00, 3.57)
			Relative Risk (95% CI)[a]	2.73 (0.54, 13.79)	
			P-value	0.2255	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	1 (0.8)	4 (3.3)
			95% CI[a]	(0.00, 2.24)	(0.12, 6.49)
			Relative Risk (95% CI)[a]	0.23 (0.03, 2.02)	
			P-value	0.1848	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	5 (4.6)	2 (1.8)
			95% CI[a]	(0.67, 8.59)	(0.00, 4.28)
			Relative Risk (95% CI)[a]	2.57 (0.51, 12.96)	
			P-value	0.2531	
			Test for interaction[b]	0.0913	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	8 (4.7)	4 (2.3)
			95% CI[a]	(1.50, 7.80)	(0.07, 4.47)
			Relative Risk (95% CI)[a]	2.05 (0.63, 6.67)	
			P-value	0.2349	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	3 (1.6)	4 (2.1)
			95% CI[a]	(0.00, 3.39)	(0.06, 4.17)
			Relative Risk (95% CI)[a]	0.75 (0.17, 3.32)	
			P-value	0.7091	
			Test for interaction[b]	0.2278	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Table 14.3.1.6.3 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	3 (3.6)	4 (3.8)
			95% CI[a]	(0.00, 7.63)	(0.15, 7.47)
			Relative Risk (95% CI)[a]	0.95 (0.22, 4.12)	
			P-value	0.9441	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	8 (2.9)	4 (1.5)
			95% CI[a]	(0.93, 4.91)	(0.04, 3.05)
			Relative Risk (95% CI)[a]	1.89 (0.58, 6.20)	
			P-value	0.2935	
			Test for interaction[b]	0.6107	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	5 (2.2)	6 (2.4)
			95% CI[a]	(0.29, 4.06)	(0.51, 4.35)
			Relative Risk (95% CI)[a]	0.89 (0.28, 2.89)	
			P-value	0.8529	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	5 (3.8)	2 (1.7)
			95% CI[a]	(0.53, 7.04)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	2.23 (0.44, 11.30)	
			P-value	0.3309	
			Test for interaction[b]	0.3408	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6_e

Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	9 (2.6)	8 (2.3)
			95% CI[a]	(0.94, 4.34)	(0.71, 3.81)
			Relative Risk (95% CI)[a]	1.17 (0.46, 2.99)	
			P-value	0.7464	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.9955	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	6 (3.1)	2 (1.0)
			95% CI[a]	(0.66, 5.56)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	3.17 (0.65, 15.52)	
			P-value	0.1544	
Sex: Female	Overall	Overall	N	169	161
			n (%)	4 (2.4)	6 (3.7)
			95% CI[a]	(0.07, 4.66)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	0.64 (0.18, 2.21)	
			P-value	0.4754	
			Test for interaction[b]	0.1439	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	9 (3.3)	6 (2.4)
			95% CI[a]	(1.20, 5.49)	(0.51, 4.33)
			Relative Risk (95% CI)[a]	1.38 (0.50, 3.83)	
			P-value	0.5327	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	1 (4.0)	0
			95% CI[a]	(0.00, 11.68)	(0.00, 13.23)
			Relative Risk (95% CI)[a]	2.12 (0.07, 60.46)	
			P-value	0.6603	
Race: Asian	Overall	Overall	N	62	83
			n (%)	0	2 (2.4)
			95% CI[a]	(0.00, 5.78)	(0.00, 5.71)
			Relative Risk (95% CI)[a]	0.33 (0.02, 7.23)	
			P-value	0.4831	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: Other	Overall	Overall	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.7489	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	5 (2.8)	6 (3.1)
			95% CI[a]	(0.38, 5.27)	(0.65, 5.50)
			Relative Risk (95% CI)[a]	0.92 (0.29, 2.96)	
			P-value	0.8861	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	5 (3.3)	2 (1.5)
			95% CI[a]	(0.46, 6.21)	(0.00, 3.60)
			Relative Risk (95% CI)[a]	2.20 (0.43, 11.15)	
			P-value	0.3410	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	0	0
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.8759	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6_e

Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	5 (2.3)	5 (2.3)
			95% CI[a]	(0.31, 4.32)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	1.02 (0.30, 3.47)	
			P-value	0.9766	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	5 (3.4)	3 (2.1)
			95% CI[a]	(0.47, 6.37)	(0.00, 4.39)
			Relative Risk (95% CI)[a]	1.66 (0.40, 6.80)	
			P-value	0.4845	
			Test for interaction[b]	0.5825	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6_e

Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	1 (2.5)	2 (3.9)
			95% CI[a]	(0.00, 7.34)	(0.00, 9.25)
			Relative Risk (95% CI)[a]	0.64 (0.06, 6.78)	
			P-value	0.7090	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	9 (2.8)	6 (1.9)
			95% CI[a]	(0.99, 4.60)	(0.40, 3.43)
			Relative Risk (95% CI)[a]	1.46 (0.53, 4.06)	
			P-value	0.4655	
			Test for interaction[b]	0.5519	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6_e

Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	6 (4.5)	4 (2.9)
			95% CI[a]	(0.99, 8.10)	(0.10, 5.78)
			Relative Risk (95% CI)[a]	1.55 (0.45, 5.35)	
			P-value	0.4922	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	4 (2.0)	1 (0.5)
			95% CI[a]	(0.06, 4.02)	(0.00, 1.61)
			Relative Risk (95% CI)[a]	3.76 (0.42, 33.29)	
			P-value	0.2347	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	0	3 (6.7)
			95% CI[a]	(0.00, 10.28)	(0.00, 13.95)
			Relative Risk (95% CI)[a]	0.22 (0.01, 4.20)	
			P-value	0.3124	
			Test for interaction[b]	0.3166	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	5 (2.3)	5 (2.3)
			95% CI[a]	(0.30, 4.20)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	0.99 (0.29, 3.38)	
			P-value	0.9885	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	5 (3.6)	3 (2.1)
			95% CI[a]	(0.50, 6.65)	(0.00, 4.39)
			Relative Risk (95% CI)[a]	1.73 (0.42, 7.09)	
			P-value	0.4487	
			Test for interaction[b]	0.5290	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6_e

Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	6 (3.3)	4 (2.2)
			95% CI[a]	(0.71, 5.92)	(0.07, 4.30)
			Relative Risk (95% CI)[a]	1.52 (0.44, 5.28)	
			P-value	0.5132	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	4 (2.3)	4 (2.3)
			95% CI[a]	(0.07, 4.58)	(0.07, 4.53)
			Relative Risk (95% CI)[a]	1.01 (0.26, 3.98)	
			P-value	0.9868	
			Test for interaction[b]	0.6393	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	5 (4.1)	2 (1.5)
			95% CI[a]	(0.58, 7.62)	(0.00, 3.57)
			Relative Risk (95% CI)[a]	2.73 (0.54, 13.79)	
			P-value	0.2255	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	1 (0.8)	4 (3.3)
			95% CI[a]	(0.00, 2.24)	(0.12, 6.49)
			Relative Risk (95% CI)[a]	0.23 (0.03, 2.02)	
			P-value	0.1848	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	4 (3.7)	2 (1.8)
			95% CI[a]	(0.14, 7.27)	(0.00, 4.28)
			Relative Risk (95% CI)[a]	2.06 (0.38, 10.99)	
			P-value	0.3996	
			Test for interaction[b]	0.1222	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	7 (4.1)	4 (2.3)
			95% CI[a]	(1.12, 7.02)	(0.07, 4.47)
			Relative Risk (95% CI)[a]	1.79 (0.53, 6.01)	
			P-value	0.3455	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	3 (1.6)	4 (2.1)
			95% CI[a]	(0.00, 3.39)	(0.06, 4.17)
			Relative Risk (95% CI)[a]	0.75 (0.17, 3.32)	
			P-value	0.7091	
			Test for interaction[b]	0.3215	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.3.1 Abrocitinib
Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	3 (3.6)	4 (3.8)
			95% CI[a]	(0.00, 7.63)	(0.15, 7.47)
			Relative Risk (95% CI)[a]	0.95 (0.22, 4.12)	
			P-value	0.9441	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	7 (2.6)	4 (1.5)
			95% CI[a]	(0.69, 4.42)	(0.04, 3.05)
			Relative Risk (95% CI)[a]	1.65 (0.49, 5.58)	
			P-value	0.4175	
			Test for interaction[b]	0.6942	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	Age (years) group: <40	N	230	247
			n (%)	129 (56.1)	87 (35.2)
			95% CI[a]	(49.67, 62.50)	(29.27, 41.18)
			Relative Risk (95% CI)[a]	1.59 (1.30, 1.95)	
			P-value	<.0001	
		Age (years) group: >=40	N	132	118
			n (%)	68 (51.5)	42 (35.6)
			95% CI[a]	(42.99, 60.04)	(26.95, 44.23)
			Relative Risk (95% CI)[a]	1.45 (1.08, 1.94)	
			P-value	0.0136	
			Test for interaction[b]	0.4642	
Gastrointestinal disorders	Overall	Age (years) group: <40	N	230	247
			n (%)	53 (23.0)	7 (2.8)
			95% CI[a]	(17.60, 28.49)	(0.76, 4.90)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	8.13 (3.77, 17.52)	
			P-value	<.0001	
		Age (years) group: >=40	N	132	118
			n (%)	17 (12.9)	4 (3.4)
			95% CI[a]	(7.16, 18.59)	(0.12, 6.66)
			Relative Risk (95% CI)[a]	3.80 (1.32, 10.97)	
			P-value	0.0136	
			Test for interaction[b]	0.0148	
	Nausea	Age (years) group: <40	N	230	247
			n (%)	53 (23.0)	5 (2.0)
			95% CI[a]	(17.60, 28.49)	(0.27, 3.78)
			Relative Risk (95% CI)[a]	11.38 (4.63, 27.98)	
			P-value	<.0001	
		Age (years) group: >=40	N	132	118
			n (%)	17 (12.9)	3 (2.5)
			95% CI[a]	(7.16, 18.59)	(0.00, 5.38)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	5.07 (1.52, 16.85)	
			P-value	0.0082	
			Test for interaction[b]	0.0132	
	Vomiting	Age (years) group: <40	N	230	247
			n (%)	9 (3.9)	4 (1.6)
			95% CI[a]	(1.41, 6.42)	(0.05, 3.19)
			Relative Risk (95% CI)[a]	2.42 (0.75, 7.74)	
			P-value	0.1374	
		Age (years) group: >=40	N	132	118
			n (%)	2 (1.5)	2 (1.7)
			95% CI[a]	(0.00, 3.60)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	0.89 (0.13, 6.25)	
			P-value	0.9100	
			Test for interaction[b]	0.2587	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
General disorders and administration site conditions	Overall	Age (years) group: <40	N	230	247
			n (%)	3 (1.3)	3 (1.2)
			95% CI[a]	(0.00, 2.77)	(0.00, 2.58)
			Relative Risk (95% CI)[a]	1.07 (0.22, 5.27)	
			P-value	0.9300	
		Age (years) group: >=40	N	132	118
			n (%)	7 (5.3)	2 (1.7)
			95% CI[a]	(1.48, 9.13)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	3.13 (0.66, 14.77)	
			P-value	0.1497	
			Test for interaction[b]	0.1610	
	Fatigue	Age (years) group: <40	N	230	247
			n (%)	3 (1.3)	3 (1.2)
			95% CI[a]	(0.00, 2.77)	(0.00, 2.58)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.07 (0.22, 5.27)	
			P-value	0.9300	
		Age (years) group: >=40	N	132	118
			n (%)	7 (5.3)	2 (1.7)
			95% CI[a]	(1.48, 9.13)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	3.13 (0.66, 14.77)	
			P-value	0.1497	
			Test for interaction[b]	0.1610	
Infections and infestations	Overall	Age (years) group: <40	N	230	247
			n (%)	44 (19.1)	48 (19.4)
			95% CI[a]	(14.05, 24.21)	(14.50, 24.37)
			Relative Risk (95% CI)[a]	0.98 (0.68, 1.42)	
			P-value	0.9333	
		Age (years) group: >=40	N	132	118
			n (%)	24 (18.2)	28 (23.7)
			95% CI[a]	(11.60, 24.76)	(16.05, 31.40)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.77 (0.47, 1.24)	
			P-value	0.2823	
			Test for interaction[b]	0.4034	
	COVID-19	Age (years) group: <40	N	230	247
			n (%)	9 (3.9)	9 (3.6)
			95% CI[a]	(1.41, 6.42)	(1.31, 5.98)
			Relative Risk (95% CI)[a]	1.07 (0.43, 2.66)	
			P-value	0.8774	
		Age (years) group: >=40	N	132	118
			n (%)	6 (4.5)	3 (2.5)
			95% CI[a]	(0.99, 8.10)	(0.00, 5.38)
			Relative Risk (95% CI)[a]	1.79 (0.46, 6.99)	
			P-value	0.4036	
			Test for interaction[b]	0.5518	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Conjunctivitis	Age (years) group: <40	N	230	247
			n (%)	4 (1.7)	20 (8.1)
			95% CI[a]	(0.05, 3.43)	(4.70, 11.50)
			Relative Risk (95% CI)[a]	0.21 (0.07, 0.62)	
			P-value	0.0044	
		Age (years) group: >=40	N	132	118
			n (%)	4 (3.0)	15 (12.7)
			95% CI[a]	(0.11, 5.95)	(6.70, 18.72)
			Relative Risk (95% CI)[a]	0.24 (0.08, 0.70)	
			P-value	0.0089	
			Test for interaction[b]	0.3803	
	Folliculitis	Age (years) group: <40	N	230	247
			n (%)	7 (3.0)	2 (0.8)
			95% CI[a]	(0.82, 5.26)	(0.00, 1.93)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	3.76 (0.79, 17.91)	
			P-value	0.0965	
		Age (years) group: >=40	N	132	118
			n (%)	5 (3.8)	1 (0.8)
			95% CI[a]	(0.53, 7.04)	(0.00, 2.50)
			Relative Risk (95% CI)[a]	4.47 (0.53, 37.71)	
			P-value	0.1688	
			Test for interaction[b]	0.7526	
	Herpes simplex	Age (years) group: <40	N	230	247
			n (%)	9 (3.9)	3 (1.2)
			95% CI[a]	(1.41, 6.42)	(0.00, 2.58)
			Relative Risk (95% CI)[a]	3.22 (0.88, 11.75)	
			P-value	0.0764	
		Age (years) group: >=40	N	132	118
			n (%)	3 (2.3)	2 (1.7)
			95% CI[a]	(0.00, 4.82)	(0.00, 4.02)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.34 (0.23, 7.89)	
			P-value	0.7456	
			Test for interaction[b]	0.3522	
	Nasopharyngitis	Age (years) group: <40	N	230	247
			n (%)	11 (4.8)	10 (4.0)
			95% CI[a]	(2.02, 7.54)	(1.59, 6.51)
			Relative Risk (95% CI)[a]	1.18 (0.51, 2.73)	
			P-value	0.6965	
		Age (years) group: >=40	N	132	118
			n (%)	3 (2.3)	2 (1.7)
			95% CI[a]	(0.00, 4.82)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	1.34 (0.23, 7.89)	
			P-value	0.7456	
			Test for interaction[b]	0.9467	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Oral herpes	Age (years) group: <40	N	230	247
			n (%)	7 (3.0)	7 (2.8)
			95% CI[a]	(0.82, 5.26)	(0.76, 4.90)
			Relative Risk (95% CI)[a]	1.07 (0.38, 3.01)	
			P-value	0.8923	
		Age (years) group: >=40	N	132	118
			n (%)	2 (1.5)	8 (6.8)
			95% CI[a]	(0.00, 3.60)	(2.24, 11.32)
			Relative Risk (95% CI)[a]	0.22 (0.05, 1.03)	
			P-value	0.0548	
			Test for interaction[b]	0.0692	
	Upper respiratory tract infection	Age (years) group: <40	N	230	247
			n (%)	6 (2.6)	7 (2.8)
			95% CI[a]	(0.55, 4.67)	(0.76, 4.90)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.92 (0.31, 2.70)	
			P-value	0.8800	
		Age (years) group: >=40	N	132	118
			n (%)	4 (3.0)	2 (1.7)
			95% CI[a]	(0.11, 5.95)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	1.79 (0.33, 9.58)	
			P-value	0.4976	
			Test for interaction[b]	0.5198	
Investigations	Overall	Age (years) group: <40	N	230	247
			n (%)	22 (9.6)	19 (7.7)
			95% CI[a]	(5.76, 13.37)	(4.37, 11.02)
			Relative Risk (95% CI)[a]	1.24 (0.69, 2.24)	
			P-value	0.4668	
		Age (years) group: >=40	N	132	118
			n (%)	16 (12.1)	7 (5.9)
			95% CI[a]	(6.55, 17.69)	(1.67, 10.19)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.04 (0.87, 4.79)	
			P-value	0.1005	
			Test for interaction[b]	0.3293	
	Blood creatine phosphokinase increased	Age (years) group: <40	N	230	247
			n (%)	5 (2.2)	10 (4.0)
			95% CI[a]	(0.29, 4.06)	(1.59, 6.51)
			Relative Risk (95% CI)[a]	0.54 (0.19, 1.55)	
			P-value	0.2495	
		Age (years) group: >=40	N	132	118
			n (%)	9 (6.8)	3 (2.5)
			95% CI[a]	(2.52, 11.12)	(0.00, 5.38)
			Relative Risk (95% CI)[a]	2.68 (0.74, 9.67)	
			P-value	0.1318	
			Test for interaction[b]	0.0468	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Natural killer cell count decreased	Age (years) group: <40	N	230	247
			n (%)	7 (3.0)	0
			95% CI[a]	(0.82, 5.26)	(0.00, 1.48)
			Relative Risk (95% CI)[a]	15.07 (0.86, 263.98)	
			P-value	0.0634	
		Age (years) group: >=40	N	132	118
			n (%)	3 (2.3)	0
			95% CI[a]	(0.00, 4.82)	(0.00, 3.08)
			Relative Risk (95% CI)[a]	5.39 (0.27, 106.43)	
			P-value	0.2687	
			Test for interaction[b]	0.5919	
	SARS-CoV-2 test positive	Age (years) group: <40	N	230	247
			n (%)	10 (4.3)	9 (3.6)
			95% CI[a]	(1.71, 6.98)	(1.31, 5.98)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.19 (0.49, 2.88)	
			P-value	0.6948	
		Age (years) group: >=40	N	132	118
			n (%)	5 (3.8)	4 (3.4)
			95% CI[a]	(0.53, 7.04)	(0.12, 6.66)
			Relative Risk (95% CI)[a]	1.12 (0.31, 4.06)	
			P-value	0.8662	
			Test for interaction[b]	0.9170	
Nervous system disorders	Overall	Age (years) group: <40	N	230	247
			n (%)	33 (14.3)	18 (7.3)
			95% CI[a]	(9.82, 18.88)	(4.05, 10.53)
			Relative Risk (95% CI)[a]	1.97 (1.14, 3.40)	
			P-value	0.0149	
		Age (years) group: >=40	N	132	118
			n (%)	22 (16.7)	9 (7.6)
			95% CI[a]	(10.31, 23.02)	(2.84, 12.42)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.19 (1.05, 4.56)	
			P-value	0.0370	
			Test for interaction[b]	0.6772	
	Dizziness	Age (years) group: <40	N	230	247
			n (%)	6 (2.6)	1 (0.4)
			95% CI[a]	(0.55, 4.67)	(0.00, 1.20)
			Relative Risk (95% CI)[a]	6.44 (0.78, 53.11)	
			P-value	0.0834	
		Age (years) group: >=40	N	132	118
			n (%)	4 (3.0)	3 (2.5)
			95% CI[a]	(0.11, 5.95)	(0.00, 5.38)
			Relative Risk (95% CI)[a]	1.19 (0.27, 5.22)	
			P-value	0.8157	
			Test for interaction[b]	0.4751	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Headache	Age (years) group: <40	N	230	247
			n (%)	28 (12.2)	17 (6.9)
			95% CI[a]	(7.95, 16.40)	(3.73, 10.04)
			Relative Risk (95% CI)[a]	1.77 (1.00, 3.14)	
			P-value	0.0520	
		Age (years) group: >=40	N	132	118
			n (%)	19 (14.4)	7 (5.9)
			95% CI[a]	(8.41, 20.38)	(1.67, 10.19)
			Relative Risk (95% CI)[a]	2.43 (1.06, 5.57)	
			P-value	0.0364	
			Test for interaction[b]	0.4922	
Skin and subcutaneous tissue disorders	Overall	Age (years) group: <40	N	230	247
			n (%)	47 (20.4)	19 (7.7)
			95% CI[a]	(15.22, 25.65)	(4.37, 11.02)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.66 (1.61, 4.39)	
			P-value	0.0001	
		Age (years) group: >=40	N	132	118
			n (%)	14 (10.6)	4 (3.4)
			95% CI[a]	(5.35, 15.86)	(0.12, 6.66)
			Relative Risk (95% CI)[a]	3.13 (1.06, 9.24)	
			P-value	0.0390	
			Test for interaction[b]	0.1683	
	Acne	Age (years) group: <40	N	230	247
			n (%)	33 (14.3)	10 (4.0)
			95% CI[a]	(9.82, 18.88)	(1.59, 6.51)
			Relative Risk (95% CI)[a]	3.54 (1.79, 7.03)	
			P-value	0.0003	
		Age (years) group: >=40	N	132	118
			n (%)	13 (9.8)	0
			95% CI[a]	(4.77, 14.93)	(0.00, 3.08)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	23.34 (1.40, 389.13)	
			P-value	0.0282	
			Test for interaction[b]	0.7370	
	Dermatitis atopic	Age (years) group: <40	N	230	247
			n (%)	16 (7.0)	10 (4.0)
			95% CI[a]	(3.67, 10.24)	(1.59, 6.51)
			Relative Risk (95% CI)[a]	1.72 (0.80, 3.71)	
			P-value	0.1679	
		Age (years) group: >=40	N	132	118
			n (%)	1 (0.8)	4 (3.4)
			95% CI[a]	(0.00, 2.24)	(0.12, 6.66)
			Relative Risk (95% CI)[a]	0.22 (0.03, 1.97)	
			P-value	0.1774	
			Test for interaction[b]	0.0481	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	Age (years) group: <65	N	341	354
			n (%)	187 (54.8)	129 (36.4)
			95% CI[a]	(49.56, 60.12)	(31.43, 41.45)
			Relative Risk (95% CI)[a]	1.50 (1.27, 1.78)	
			P-value	<.0001	
		Age (years) group: >=65	N	21	11
			n (%)	10 (47.6)	0
			95% CI[a]	(26.26, 68.98)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	10.95 (0.70, 170.94)	
			P-value	0.0878	
			Test for interaction[b]	0.2553	
Gastrointestinal disorders	Overall	Age (years) group: <65	N	341	354
			n (%)	68 (19.9)	11 (3.1)
			95% CI[a]	(15.70, 24.18)	(1.30, 4.91)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	6.42 (3.45, 11.92)	
			P-value	<.0001	
		Age (years) group: >=65	N	21	11
			n (%)	2 (9.5)	0
			95% CI[a]	(0.00, 22.08)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	2.19 (0.11, 44.64)	
			P-value	0.6102	
			Test for interaction[b]	0.1717	
	Nausea	Age (years) group: <65	N	341	354
			n (%)	68 (19.9)	8 (2.3)
			95% CI[a]	(15.70, 24.18)	(0.71, 3.81)
			Relative Risk (95% CI)[a]	8.82 (4.31, 18.08)	
			P-value	<.0001	
		Age (years) group: >=65	N	21	11
			n (%)	2 (9.5)	0
			95% CI[a]	(0.00, 22.08)	(0.00, 28.49)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.19 (0.11, 44.64)	
			P-value	0.6102	
			Test for interaction[b]	0.1452	
	Vomiting	Age (years) group: <65	N	341	354
			n (%)	10 (2.9)	6 (1.7)
			95% CI[a]	(1.14, 4.72)	(0.35, 3.04)
			Relative Risk (95% CI)[a]	1.73 (0.64, 4.71)	
			P-value	0.2831	
		Age (years) group: >=65	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.9175	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
General disorders and administration site conditions	Overall	Age (years) group: <65	N	341	354
			n (%)	8 (2.3)	5 (1.4)
			95% CI[a]	(0.74, 3.95)	(0.18, 2.64)
			Relative Risk (95% CI)[a]	1.66 (0.55, 5.03)	
			P-value	0.3692	
		Age (years) group: >=65	N	21	11
			n (%)	2 (9.5)	0
			95% CI[a]	(0.00, 22.08)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	2.19 (0.11, 44.64)	
			P-value	0.6102	
			Test for interaction[b]	0.6283	
	Fatigue	Age (years) group: <65	N	341	354
			n (%)	8 (2.3)	5 (1.4)
			95% CI[a]	(0.74, 3.95)	(0.18, 2.64)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.66 (0.55, 5.03)	
			P-value	0.3692	
		Age (years) group: >=65	N	21	11
			n (%)	2 (9.5)	0
			95% CI[a]	(0.00, 22.08)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	2.19 (0.11, 44.64)	
			P-value	0.6102	
			Test for interaction[b]	0.6283	
Infections and infestations	Overall	Age (years) group: <65	N	341	354
			n (%)	64 (18.8)	76 (21.5)
			95% CI[a]	(14.62, 22.91)	(17.19, 25.75)
			Relative Risk (95% CI)[a]	0.87 (0.65, 1.18)	
			P-value	0.3756	
		Age (years) group: >=65	N	21	11
			n (%)	4 (19.0)	0
			95% CI[a]	(2.25, 35.84)	(0.00, 28.49)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	4.38 (0.25, 75.79)	
			P-value	0.3098	
			Test for interaction[b]	0.1194	
	COVID-19	Age (years) group: <65	N	341	354
			n (%)	14 (4.1)	12 (3.4)
			95% CI[a]	(2.00, 6.21)	(1.50, 5.27)
			Relative Risk (95% CI)[a]	1.21 (0.57, 2.58)	
			P-value	0.6197	
		Age (years) group: >=65	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.9695	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Conjunctivitis	Age (years) group: <65	N	341	354
			n (%)	8 (2.3)	35 (9.9)
			95% CI[a]	(0.74, 3.95)	(6.78, 13.00)
			Relative Risk (95% CI)[a]	0.24 (0.11, 0.50)	
			P-value	0.0002	
		Age (years) group: >=65	N	21	11
			n (%)	0	0
			Test for interaction[b]	NE	
	Folliculitis	Age (years) group: <65	N	341	354
			n (%)	11 (3.2)	3 (0.8)
			95% CI[a]	(1.35, 5.10)	(0.00, 1.80)
			Relative Risk (95% CI)[a]	3.81 (1.07, 13.53)	
			P-value	0.0388	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Age (years) group: >=65	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.8040	
	Herpes simplex	Age (years) group: <65	N	341	354
			n (%)	11 (3.2)	5 (1.4)
			95% CI[a]	(1.35, 5.10)	(0.18, 2.64)
			Relative Risk (95% CI)[a]	2.28 (0.80, 6.50)	
			P-value	0.1220	
		Age (years) group: >=65	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.8596	
	Nasopharyngitis	Age (years) group: <65	N	341	354
			n (%)	13 (3.8)	12 (3.4)
			95% CI[a]	(1.78, 5.84)	(1.50, 5.27)
			Relative Risk (95% CI)[a]	1.12 (0.52, 2.43)	
			P-value	0.7651	
		Age (years) group: >=65	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.9996	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Oral herpes	Age (years) group: <65	N	341	354
			n (%)	9 (2.6)	15 (4.2)
			95% CI[a]	(0.94, 4.34)	(2.14, 6.34)
			Relative Risk (95% CI)[a]	0.62 (0.28, 1.40)	
			P-value	0.2537	
		Age (years) group: >=65	N	21	11
			n (%)	0	0
			Test for interaction[b]	NE	
	Upper respiratory tract infection	Age (years) group: <65	N	341	354
			n (%)	10 (2.9)	9 (2.5)
			95% CI[a]	(1.14, 4.72)	(0.90, 4.18)
			Relative Risk (95% CI)[a]	1.15 (0.47, 2.80)	
			P-value	0.7527	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Age (years) group: >=65	N	21	11
			n (%)	0	0
			Test for interaction[b]	NE	
Investigations	Overall	Age (years) group: <65	N	341	354
			n (%)	37 (10.9)	26 (7.3)
			95% CI[a]	(7.55, 14.15)	(4.63, 10.06)
			Relative Risk (95% CI)[a]	1.48 (0.92, 2.39)	
			P-value	0.1103	
		Age (years) group: >=65	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.6806	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Blood creatine phosphokinase increased	Age (years) group: <65	N	341	354
			n (%)	13 (3.8)	13 (3.7)
			95% CI[a]	(1.78, 5.84)	(1.71, 5.63)
			Relative Risk (95% CI)[a]	1.04 (0.49, 2.21)	
			P-value	0.9225	
		Age (years) group: >=65	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.9716	
	Natural killer cell count decreased	Age (years) group: <65	N	341	354
			n (%)	10 (2.9)	0
			95% CI[a]	(1.14, 4.72)	(0.00, 1.04)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	20.79 (1.22, 354.58)	
			P-value	0.0360	
		Age (years) group: >=65	N	21	11
			n (%)	0	0
			Test for interaction[b]	NE	
	SARS-CoV-2 test positive	Age (years) group: <65	N	341	354
			n (%)	15 (4.4)	13 (3.7)
			95% CI[a]	(2.22, 6.58)	(1.71, 5.63)
			Relative Risk (95% CI)[a]	1.20 (0.58, 2.48)	
			P-value	0.6268	
		Age (years) group: >=65	N	21	11
			n (%)	0	0
			Test for interaction[b]	NE	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Nervous system disorders	Overall	Age (years) group: <65	N	341	354
			n (%)	52 (15.2)	27 (7.6)
			95% CI[a]	(11.43, 19.06)	(4.86, 10.39)
			Relative Risk (95% CI)[a]	2.00 (1.29, 3.11)	
			P-value	0.0021	
		Age (years) group: >=65	N	21	11
			n (%)	3 (14.3)	0
			95% CI[a]	(0.00, 29.25)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	3.29 (0.18, 60.09)	
			P-value	0.4224	
			Test for interaction[b]	0.8339	
	Dizziness	Age (years) group: <65	N	341	354
			n (%)	9 (2.6)	4 (1.1)
			95% CI[a]	(0.94, 4.34)	(0.03, 2.23)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.34 (0.73, 7.51)	
			P-value	0.1547	
		Age (years) group: >=65	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.8906	
	Headache	Age (years) group: <65	N	341	354
			n (%)	44 (12.9)	24 (6.8)
			95% CI[a]	(9.35, 16.46)	(4.16, 9.40)
			Relative Risk (95% CI)[a]	1.90 (1.18, 3.06)	
			P-value	0.0079	
		Age (years) group: >=65	N	21	11
			n (%)	3 (14.3)	0
			95% CI[a]	(0.00, 29.25)	(0.00, 28.49)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	3.29 (0.18, 60.09)	
			P-value	0.4224	
			Test for interaction[b]	0.7091	
Skin and subcutaneous tissue disorders	Overall	Age (years) group: <65	N	341	354
			n (%)	61 (17.9)	23 (6.5)
			95% CI[a]	(13.82, 21.96)	(3.93, 9.06)
			Relative Risk (95% CI)[a]	2.75 (1.75, 4.34)	
			P-value	<.0001	
		Age (years) group: >=65	N	21	11
			n (%)	0	0
			Test for interaction[b]	NE	
	Acne	Age (years) group: <65	N	341	354
			n (%)	46 (13.5)	10 (2.8)
			95% CI[a]	(9.86, 17.12)	(1.10, 4.55)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	4.78 (2.45, 9.31)	
			P-value	<.0001	
		Age (years) group: >=65	N	21	11
			n (%)	0	0
			Test for interaction[b]	NE	
	Dermatitis atopic	Age (years) group: <65	N	341	354
			n (%)	17 (5.0)	14 (4.0)
			95% CI[a]	(2.68, 7.30)	(1.92, 5.99)
			Relative Risk (95% CI)[a]	1.26 (0.63, 2.52)	
			P-value	0.5116	
		Age (years) group: >=65	N	21	11
			n (%)	0	0
			Test for interaction[b]	NE	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	Sex: Male	N	193	204
			n (%)	100 (51.8)	68 (33.3)
			95% CI[a]	(44.76, 58.86)	(26.86, 39.80)
			Relative Risk (95% CI)[a]	1.55 (1.23, 1.97)	
			P-value	0.0003	
		Sex: Female	N	169	161
			n (%)	97 (57.4)	61 (37.9)
			95% CI[a]	(49.94, 64.85)	(30.39, 45.38)
			Relative Risk (95% CI)[a]	1.51 (1.20, 1.92)	
			P-value	0.0006	
			Test for interaction[b]	0.7096	
Gastrointestinal disorders	Overall	Sex: Male	N	193	204
			n (%)	21 (10.9)	4 (2.0)
			95% CI[a]	(6.49, 15.27)	(0.06, 3.86)
			Relative Risk (95% CI)[a]	5.55 (1.94, 15.87)	
			P-value	0.0014	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Sex: Female	N	169	161
			n (%)	49 (29.0)	7 (4.3)
			95% CI[a]	(22.15, 35.83)	(1.20, 7.50)
			Relative Risk (95% CI)[a]	6.67 (3.11, 14.29)	
			P-value	<.0001	
			Test for interaction[b]	0.0005	
	Nausea	Sex: Male	N	193	204
			n (%)	21 (10.9)	2 (1.0)
			95% CI[a]	(6.49, 15.27)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	11.10 (2.64, 46.70)	
			P-value	0.0010	
		Sex: Female	N	169	161
			n (%)	49 (29.0)	6 (3.7)
			95% CI[a]	(22.15, 35.83)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	7.78 (3.43, 17.66)	
			P-value	<.0001	
			Test for interaction[b]	0.0006	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Vomiting	Sex: Male	N	193	204
			n (%)	2 (1.0)	3 (1.5)
			95% CI[a]	(0.00, 2.46)	(0.00, 3.12)
			Relative Risk (95% CI)[a]	0.70 (0.12, 4.17)	
			P-value	0.6997	
		Sex: Female	N	169	161
			n (%)	9 (5.3)	3 (1.9)
			95% CI[a]	(1.94, 8.71)	(0.00, 3.95)
			Relative Risk (95% CI)[a]	2.86 (0.79, 10.37)	
			P-value	0.1102	
			Test for interaction[b]	0.0936	
General disorders and administration site conditions	Overall	Sex: Male	N	193	204
			n (%)	3 (1.6)	3 (1.5)
			95% CI[a]	(0.00, 3.30)	(0.00, 3.12)
			Relative Risk (95% CI)[a]	1.06 (0.22, 5.17)	
			P-value	0.9455	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Sex: Female	N	169	161
			n (%)	7 (4.1)	2 (1.2)
			95% CI[a]	(1.14, 7.15)	(0.00, 2.95)
			Relative Risk (95% CI)[a]	3.33 (0.70, 15.81)	
			P-value	0.1294	
			Test for interaction[b]	0.1904	
	Fatigue	Sex: Male	N	193	204
			n (%)	3 (1.6)	3 (1.5)
			95% CI[a]	(0.00, 3.30)	(0.00, 3.12)
			Relative Risk (95% CI)[a]	1.06 (0.22, 5.17)	
			P-value	0.9455	
		Sex: Female	N	169	161
			n (%)	7 (4.1)	2 (1.2)
			95% CI[a]	(1.14, 7.15)	(0.00, 2.95)
			Relative Risk (95% CI)[a]	3.33 (0.70, 15.81)	
			P-value	0.1294	
			Test for interaction[b]	0.1904	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Infections and infestations	Overall	Sex: Male	N	193	204
			n (%)	40 (20.7)	41 (20.1)
			95% CI[a]	(15.01, 26.44)	(14.60, 25.60)
			Relative Risk (95% CI)[a]	1.03 (0.70, 1.52)	
			P-value	0.8768	
		Sex: Female	N	169	161
			n (%)	28 (16.6)	35 (21.7)
			95% CI[a]	(10.96, 22.17)	(15.37, 28.11)
			Relative Risk (95% CI)[a]	0.76 (0.49, 1.19)	
			P-value	0.2343	
			Test for interaction[b]	0.3320	
	COVID-19	Sex: Male	N	193	204
			n (%)	7 (3.6)	5 (2.5)
			95% CI[a]	(0.99, 6.26)	(0.33, 4.57)
			Relative Risk (95% CI)[a]	1.48 (0.48, 4.58)	
			P-value	0.4969	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Sex: Female	N	169	161
			n (%)	8 (4.7)	7 (4.3)
			95% CI[a]	(1.53, 7.94)	(1.20, 7.50)
			Relative Risk (95% CI)[a]	1.09 (0.40, 2.93)	
			P-value	0.8665	
			Test for interaction[b]	0.7869	
	Conjunctivitis	Sex: Male	N	193	204
			n (%)	7 (3.6)	20 (9.8)
			95% CI[a]	(0.99, 6.26)	(5.72, 13.88)
			Relative Risk (95% CI)[a]	0.37 (0.16, 0.86)	
			P-value	0.0200	
		Sex: Female	N	169	161
			n (%)	1 (0.6)	15 (9.3)
			95% CI[a]	(0.00, 1.75)	(4.83, 13.81)
			Relative Risk (95% CI)[a]	0.06 (0.01, 0.48)	
			P-value	0.0073	
			Test for interaction[b]	0.4937	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Folliculitis	Sex: Male	N	193	204
			n (%)	10 (5.2)	2 (1.0)
			95% CI[a]	(2.05, 8.31)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	5.28 (1.17, 23.81)	
			P-value	0.0302	
		Sex: Female	N	169	161
			n (%)	2 (1.2)	1 (0.6)
			95% CI[a]	(0.00, 2.81)	(0.00, 1.83)
			Relative Risk (95% CI)[a]	1.91 (0.17, 20.81)	
			P-value	0.5972	
			Test for interaction[b]	0.0729	
	Herpes simplex	Sex: Male	N	193	204
			n (%)	8 (4.1)	2 (1.0)
			95% CI[a]	(1.33, 6.96)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	4.23 (0.91, 19.66)	
			P-value	0.0660	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Sex: Female	N	169	161
			n (%)	4 (2.4)	3 (1.9)
			95% CI[a]	(0.07, 4.66)	(0.00, 3.95)
			Relative Risk (95% CI)[a]	1.27 (0.29, 5.59)	
			P-value	0.7516	
			Test for interaction[b]	0.2368	
	Nasopharyngitis	Sex: Male	N	193	204
			n (%)	7 (3.6)	7 (3.4)
			95% CI[a]	(0.99, 6.26)	(0.93, 5.93)
			Relative Risk (95% CI)[a]	1.06 (0.38, 2.96)	
			P-value	0.9159	
		Sex: Female	N	169	161
			n (%)	7 (4.1)	5 (3.1)
			95% CI[a]	(1.14, 7.15)	(0.43, 5.79)
			Relative Risk (95% CI)[a]	1.33 (0.43, 4.12)	
			P-value	0.6165	
			Test for interaction[b]	0.7611	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Oral herpes	Sex: Male	N	193	204
			n (%)	3 (1.6)	7 (3.4)
			95% CI[a]	(0.00, 3.30)	(0.93, 5.93)
			Relative Risk (95% CI)[a]	0.45 (0.12, 1.73)	
			P-value	0.2461	
		Sex: Female	N	169	161
			n (%)	6 (3.6)	8 (5.0)
			95% CI[a]	(0.76, 6.34)	(1.61, 8.33)
			Relative Risk (95% CI)[a]	0.71 (0.25, 2.01)	
			P-value	0.5249	
			Test for interaction[b]	0.8754	
	Upper respiratory tract infection	Sex: Male	N	193	204
			n (%)	6 (3.1)	3 (1.5)
			95% CI[a]	(0.66, 5.56)	(0.00, 3.12)
			Relative Risk (95% CI)[a]	2.11 (0.54, 8.33)	
			P-value	0.2849	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Sex: Female	N	169	161
			n (%)	4 (2.4)	6 (3.7)
			95% CI[a]	(0.07, 4.66)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	0.64 (0.18, 2.21)	
			P-value	0.4754	
			Test for interaction[b]	0.2174	
Investigations	Overall	Sex: Male	N	193	204
			n (%)	21 (10.9)	12 (5.9)
			95% CI[a]	(6.49, 15.27)	(2.65, 9.11)
			Relative Risk (95% CI)[a]	1.85 (0.94, 3.66)	
			P-value	0.0769	
		Sex: Female	N	169	161
			n (%)	17 (10.1)	14 (8.7)
			95% CI[a]	(5.52, 14.59)	(4.34, 13.05)
			Relative Risk (95% CI)[a]	1.16 (0.59, 2.27)	
			P-value	0.6717	
			Test for interaction[b]	0.3986	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Blood creatine phosphokinase increased	Sex: Male	N	193	204
			n (%)	9 (4.7)	7 (3.4)
			95% CI[a]	(1.69, 7.64)	(0.93, 5.93)
			Relative Risk (95% CI)[a]	1.36 (0.52, 3.58)	
			P-value	0.5345	
		Sex: Female	N	169	161
			n (%)	5 (3.0)	6 (3.7)
			95% CI[a]	(0.40, 5.51)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	0.79 (0.25, 2.55)	
			P-value	0.6983	
			Test for interaction[b]	0.4755	
	Natural killer cell count decreased	Sex: Male	N	193	204
			n (%)	5 (2.6)	0
			95% CI[a]	(0.35, 4.83)	(0.00, 1.79)
			Relative Risk (95% CI)[a]	10.60 (0.58, 192.65)	
			P-value	0.1107	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Sex: Female	N	169	161
			n (%)	5 (3.0)	0
			95% CI[a]	(0.40, 5.51)	(0.00, 2.27)
			Relative Risk (95% CI)[a]	9.56 (0.53, 173.52)	
			P-value	0.1270	
			Test for interaction[b]	0.8670	
	SARS-CoV-2 test positive	Sex: Male	N	193	204
			n (%)	7 (3.6)	5 (2.5)
			95% CI[a]	(0.99, 6.26)	(0.33, 4.57)
			Relative Risk (95% CI)[a]	1.48 (0.48, 4.58)	
			P-value	0.4969	
		Sex: Female	N	169	161
			n (%)	8 (4.7)	8 (5.0)
			95% CI[a]	(1.53, 7.94)	(1.61, 8.33)
			Relative Risk (95% CI)[a]	0.95 (0.37, 2.48)	
			P-value	0.9208	
			Test for interaction[b]	0.6334	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Nervous system disorders	Overall	Sex: Male	N	193	204
			n (%)	28 (14.5)	12 (5.9)
			95% CI[a]	(9.54, 19.48)	(2.65, 9.11)
			Relative Risk (95% CI)[a]	2.47 (1.29, 4.71)	
			P-value	0.0062	
		Sex: Female	N	169	161
			n (%)	27 (16.0)	15 (9.3)
			95% CI[a]	(10.45, 21.50)	(4.83, 13.81)
			Relative Risk (95% CI)[a]	1.71 (0.95, 3.10)	
			P-value	0.0747	
			Test for interaction[b]	0.7148	
	Dizziness	Sex: Male	N	193	204
			n (%)	4 (2.1)	2 (1.0)
			95% CI[a]	(0.06, 4.08)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	2.11 (0.39, 11.41)	
			P-value	0.3842	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Sex: Female	N	169	161
			n (%)	6 (3.6)	2 (1.2)
			95% CI[a]	(0.76, 6.34)	(0.00, 2.95)
			Relative Risk (95% CI)[a]	2.86 (0.59, 13.95)	
			P-value	0.1943	
			Test for interaction[b]	0.5557	
	Headache	Sex: Male	N	193	204
			n (%)	24 (12.4)	10 (4.9)
			95% CI[a]	(7.78, 17.09)	(1.94, 7.86)
			Relative Risk (95% CI)[a]	2.54 (1.25, 5.16)	
			P-value	0.0103	
		Sex: Female	N	169	161
			n (%)	23 (13.6)	14 (8.7)
			95% CI[a]	(8.44, 18.78)	(4.34, 13.05)
			Relative Risk (95% CI)[a]	1.57 (0.83, 2.93)	
			P-value	0.1623	
			Test for interaction[b]	0.5872	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Skin and subcutaneous tissue disorders	Overall	Sex: Male	N	193	204
			n (%)	34 (17.6)	12 (5.9)
			95% CI[a]	(12.24, 22.99)	(2.65, 9.11)
			Relative Risk (95% CI)[a]	2.99 (1.60, 5.61)	
			P-value	0.0006	
		Sex: Female	N	169	161
			n (%)	27 (16.0)	11 (6.8)
			95% CI[a]	(10.45, 21.50)	(2.94, 10.73)
			Relative Risk (95% CI)[a]	2.34 (1.20, 4.56)	
			P-value	0.0126	
			Test for interaction[b]	0.5853	
	Acne	Sex: Male	N	193	204
			n (%)	24 (12.4)	4 (2.0)
			95% CI[a]	(7.78, 17.09)	(0.06, 3.86)
			Relative Risk (95% CI)[a]	6.34 (2.24, 17.94)	
			P-value	0.0005	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Sex: Female	N	169	161
			n (%)	22 (13.0)	6 (3.7)
			95% CI[a]	(7.94, 18.09)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	3.49 (1.45, 8.39)	
			P-value	0.0052	
			Test for interaction[b]	0.7950	
	Dermatitis atopic	Sex: Male	N	193	204
			n (%)	11 (5.7)	8 (3.9)
			95% CI[a]	(2.43, 8.97)	(1.26, 6.59)
			Relative Risk (95% CI)[a]	1.45 (0.60, 3.54)	
			P-value	0.4099	
		Sex: Female	N	169	161
			n (%)	6 (3.6)	6 (3.7)
			95% CI[a]	(0.76, 6.34)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	0.95 (0.31, 2.89)	
			P-value	0.9318	
			Test for interaction[b]	0.5105	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	Race: White	N	269	248
			n (%)	148 (55.0)	98 (39.5)
			95% CI[a]	(49.07, 60.96)	(33.43, 45.60)
			Relative Risk (95% CI)[a]	1.39 (1.15, 1.68)	
			P-value	0.0006	
		Race: Black Or African American	N	25	26
			n (%)	11 (44.0)	5 (19.2)
			95% CI[a]	(24.54, 63.46)	(4.08, 34.38)
			Relative Risk (95% CI)[a]	2.29 (0.93, 5.65)	
			P-value	0.0725	
		Race: Asian	N	62	83
			n (%)	33 (53.2)	23 (27.7)
			95% CI[a]	(40.81, 65.65)	(18.08, 37.34)
			Relative Risk (95% CI)[a]	1.92 (1.26, 2.92)	
			P-value	0.0022	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Race: Other	N	6	8
			n (%)	5 (83.3)	3 (37.5)
			95% CI[a]	(53.51, 100.00)	(3.95, 71.05)
			Relative Risk (95% CI)[a]	2.22 (0.85, 5.82)	
			P-value	0.1043	
			Test for interaction[b]	0.6277	
Gastrointestinal disorders	Overall	Race: White	N	269	248
			n (%)	53 (19.7)	10 (4.0)
			95% CI[a]	(14.95, 24.46)	(1.58, 6.48)
			Relative Risk (95% CI)[a]	4.89 (2.54, 9.39)	
			P-value	<.0001	
		Race: Black Or African American	N	25	26
			n (%)	4 (16.0)	0
			95% CI[a]	(1.63, 30.37)	(0.00, 13.23)
			Relative Risk (95% CI)[a]	8.48 (0.47, 152.39)	
			P-value	0.1469	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Race: Asian	N	62	83
			n (%)	12 (19.4)	1 (1.2)
			95% CI[a]	(9.52, 29.19)	(0.00, 3.55)
			Relative Risk (95% CI)[a]	16.06 (2.15, 120.29)	
			P-value	0.0069	
		Race: Other	N	6	8
			n (%)	1 (16.7)	0
			95% CI[a]	(0.00, 46.49)	(0.00, 36.94)
			Relative Risk (95% CI)[a]	2.83 (0.11, 71.62)	
			P-value	0.5274	
			Test for interaction[b]	0.9617	
	Nausea	Race: White	N	269	248
			n (%)	53 (19.7)	8 (3.2)
			95% CI[a]	(14.95, 24.46)	(1.03, 5.42)
			Relative Risk (95% CI)[a]	6.11 (2.96, 12.59)	
			P-value	<.0001	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Race: Black Or African American	N	25	26
			n (%)	4 (16.0)	0
			95% CI[a]	(1.63, 30.37)	(0.00, 13.23)
			Relative Risk (95% CI)[a]	8.48 (0.47, 152.39)	
			P-value	0.1469	
		Race: Asian	N	62	83
			n (%)	12 (19.4)	0
			95% CI[a]	(9.52, 29.19)	(0.00, 4.35)
			Relative Risk (95% CI)[a]	32.32 (1.95, 536.78)	
			P-value	0.0153	
		Race: Other	N	6	8
			n (%)	1 (16.7)	0
			95% CI[a]	(0.00, 46.49)	(0.00, 36.94)
			Relative Risk (95% CI)[a]	2.83 (0.11, 71.62)	
			P-value	0.5274	
			Test for interaction[b]	0.9505	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Vomiting	Race: White	N	269	248
			n (%)	9 (3.3)	5 (2.0)
			95% CI[a]	(1.20, 5.49)	(0.27, 3.77)
			Relative Risk (95% CI)[a]	1.66 (0.56, 4.88)	
			P-value	0.3578	
		Race: Black Or African American	N	25	26
			n (%)	1 (4.0)	0
			95% CI[a]	(0.00, 11.68)	(0.00, 13.23)
			Relative Risk (95% CI)[a]	2.12 (0.07, 60.46)	
			P-value	0.6603	
		Race: Asian	N	62	83
			n (%)	1 (1.6)	1 (1.2)
			95% CI[a]	(0.00, 4.75)	(0.00, 3.55)
			Relative Risk (95% CI)[a]	1.34 (0.09, 20.99)	
			P-value	0.8354	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.9776	
General disorders and administration site conditions	Overall	Race: White	N	269	248
			n (%)	9 (3.3)	5 (2.0)
			95% CI[a]	(1.20, 5.49)	(0.27, 3.77)
			Relative Risk (95% CI)[a]	1.66 (0.56, 4.88)	
			P-value	0.3578	
		Race: Black Or African American	N	25	26
			n (%)	0	0
		Race: Asian	N	62	83
			n (%)	1 (1.6)	0
			95% CI[a]	(0.00, 4.75)	(0.00, 4.35)
			Relative Risk (95% CI)[a]	2.69 (0.09, 79.02)	
			P-value	0.5654	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.9911	
	Fatigue	Race: White	N	269	248
			n (%)	9 (3.3)	5 (2.0)
			95% CI[a]	(1.20, 5.49)	(0.27, 3.77)
			Relative Risk (95% CI)[a]	1.66 (0.56, 4.88)	
			P-value	0.3578	
		Race: Black Or African American	N	25	26
			n (%)	0	0
		Race: Asian	N	62	83
			n (%)	1 (1.6)	0
			95% CI[a]	(0.00, 4.75)	(0.00, 4.35)
			Relative Risk (95% CI)[a]	2.69 (0.09, 79.02)	
			P-value	0.5654	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.9911	
Infections and infestations	Overall	Race: White	N	269	248
			n (%)	58 (21.6)	62 (25.0)
			95% CI[a]	(16.65, 26.48)	(19.61, 30.39)
			Relative Risk (95% CI)[a]	0.86 (0.63, 1.18)	
			P-value	0.3552	
		Race: Black Or African American	N	25	26
			n (%)	2 (8.0)	2 (7.7)
			95% CI[a]	(0.00, 18.63)	(0.00, 17.93)
			Relative Risk (95% CI)[a]	1.04 (0.16, 6.83)	
			P-value	0.9674	
		Race: Asian	N	62	83
			n (%)	7 (11.3)	10 (12.0)
			95% CI[a]	(3.41, 19.17)	(5.05, 19.05)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.94 (0.38, 2.32)	
			P-value	0.8885	
		Race: Other	N	6	8
			n (%)	1 (16.7)	2 (25.0)
			95% CI[a]	(0.00, 46.49)	(0.00, 55.01)
			Relative Risk (95% CI)[a]	0.67 (0.08, 5.75)	
			P-value	0.7122	
			Test for interaction[b]	0.9309	
	COVID-19	Race: White	N	269	248
			n (%)	13 (4.8)	10 (4.0)
			95% CI[a]	(2.27, 7.40)	(1.58, 6.48)
			Relative Risk (95% CI)[a]	1.20 (0.54, 2.68)	
			P-value	0.6597	
		Race: Black Or African American	N	25	26
			n (%)	1 (4.0)	2 (7.7)
			95% CI[a]	(0.00, 11.68)	(0.00, 17.93)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.52 (0.05, 5.38)	
			P-value	0.5834	
		Race: Asian	N	62	83
			n (%)	1 (1.6)	0
			95% CI[a]	(0.00, 4.75)	(0.00, 4.35)
			Relative Risk (95% CI)[a]	2.69 (0.09, 79.02)	
			P-value	0.5654	
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.9234	
	Conjunctivitis	Race: White	N	269	248
			n (%)	6 (2.2)	30 (12.1)
			95% CI[a]	(0.47, 4.00)	(8.04, 16.16)
			Relative Risk (95% CI)[a]	0.18 (0.08, 0.44)	
			P-value	0.0001	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Race: Black Or African American	N	25	26
			n (%)	0	0
		Race: Asian	N	62	83
			n (%)	2 (3.2)	4 (4.8)
			95% CI[a]	(0.00, 7.62)	(0.21, 9.43)
			Relative Risk (95% CI)[a]	0.67 (0.13, 3.54)	
			P-value	0.6366	
		Race: Other	N	6	8
			n (%)	0	1 (12.5)
			95% CI[a]	(0.00, 45.93)	(0.00, 35.42)
			Relative Risk (95% CI)[a]	0.62 (0.02, 15.61)	
			P-value	0.7685	
			Test for interaction[b]	0.0592	
	Folliculitis	Race: White	N	269	248
			n (%)	10 (3.7)	0
			95% CI[a]	(1.46, 5.98)	(0.00, 1.48)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	18.48 (1.08, 314.66)	
			P-value	0.0438	
		Race: Black Or African American	N	25	26
			n (%)	0	1 (3.8)
			95% CI[a]	(0.00, 13.72)	(0.00, 11.24)
			Relative Risk (95% CI)[a]	0.51 (0.02, 14.54)	
			P-value	0.6935	
		Race: Asian	N	62	83
			n (%)	2 (3.2)	2 (2.4)
			95% CI[a]	(0.00, 7.62)	(0.00, 5.71)
			Relative Risk (95% CI)[a]	1.34 (0.19, 9.24)	
			P-value	0.7673	
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.6077	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Herpes simplex	Race: White	N	269	248
			n (%)	11 (4.1)	4 (1.6)
			95% CI[a]	(1.72, 6.46)	(0.05, 3.18)
			Relative Risk (95% CI)[a]	2.54 (0.82, 7.86)	
			P-value	0.1070	
		Race: Black Or African American	N	25	26
			n (%)	1 (4.0)	0
			95% CI[a]	(0.00, 11.68)	(0.00, 13.23)
			Relative Risk (95% CI)[a]	2.12 (0.07, 60.46)	
			P-value	0.6603	
		Race: Asian	N	62	83
			n (%)	0	0
		Race: Other	N	6	8
			n (%)	0	1 (12.5)
			95% CI[a]	(0.00, 45.93)	(0.00, 35.42)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.62 (0.02, 15.61)	
			P-value	0.7685	
			Test for interaction[b]	0.6895	
	Nasopharyngitis	Race: White	N	269	248
			n (%)	13 (4.8)	10 (4.0)
			95% CI[a]	(2.27, 7.40)	(1.58, 6.48)
			Relative Risk (95% CI)[a]	1.20 (0.54, 2.68)	
			P-value	0.6597	
		Race: Black Or African American	N	25	26
			n (%)	0	0
		Race: Asian	N	62	83
			n (%)	0	2 (2.4)
			95% CI[a]	(0.00, 5.78)	(0.00, 5.71)
			Relative Risk (95% CI)[a]	0.33 (0.02, 7.23)	
			P-value	0.4831	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Race: Other	N	6	8
			n (%)	1 (16.7)	0
			95% CI[a]	(0.00, 46.49)	(0.00, 36.94)
			Relative Risk (95% CI)[a]	2.83 (0.11, 71.62)	
			P-value	0.5274	
			Test for interaction[b]	0.7614	
	Oral herpes	Race: White	N	269	248
			n (%)	8 (3.0)	13 (5.2)
			95% CI[a]	(0.94, 5.00)	(2.47, 8.02)
			Relative Risk (95% CI)[a]	0.57 (0.24, 1.35)	
			P-value	0.1984	
		Race: Black Or African American	N	25	26
			n (%)	0	0
		Race: Asian	N	62	83
			n (%)	1 (1.6)	2 (2.4)
			95% CI[a]	(0.00, 4.75)	(0.00, 5.71)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.67 (0.06, 7.22)	
			P-value	0.7407	
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.9125	
	Upper respiratory tract infection	Race: White	N	269	248
			n (%)	8 (3.0)	8 (3.2)
			95% CI[a]	(0.94, 5.00)	(1.03, 5.42)
			Relative Risk (95% CI)[a]	0.92 (0.35, 2.42)	
			P-value	0.8688	
		Race: Black Or African American	N	25	26
			n (%)	0	0
		Race: Asian	N	62	83
			n (%)	2 (3.2)	1 (1.2)
			95% CI[a]	(0.00, 7.62)	(0.00, 3.55)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.68 (0.25, 28.87)	
			P-value	0.4169	
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.8969	
Investigations	Overall	Race: White	N	269	248
			n (%)	32 (11.9)	20 (8.1)
			95% CI[a]	(8.03, 15.76)	(4.68, 11.45)
			Relative Risk (95% CI)[a]	1.48 (0.87, 2.51)	
			P-value	0.1516	
		Race: Black Or African American	N	25	26
			n (%)	4 (16.0)	5 (19.2)
			95% CI[a]	(1.63, 30.37)	(4.08, 34.38)
			Relative Risk (95% CI)[a]	0.83 (0.25, 2.75)	
			P-value	0.7628	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Race: Asian	N	62	83
			n (%)	2 (3.2)	1 (1.2)
			95% CI[a]	(0.00, 7.62)	(0.00, 3.55)
			Relative Risk (95% CI)[a]	2.68 (0.25, 28.87)	
			P-value	0.4169	
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.8968	
	Blood creatine phosphokinase increased	Race: White	N	269	248
			n (%)	9 (3.3)	9 (3.6)
			95% CI[a]	(1.20, 5.49)	(1.30, 5.96)
			Relative Risk (95% CI)[a]	0.92 (0.37, 2.29)	
			P-value	0.8607	
		Race: Black Or African American	N	25	26
			n (%)	3 (12.0)	3 (11.5)
			95% CI[a]	(0.00, 24.74)	(0.00, 23.82)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.04 (0.23, 4.68)	
			P-value	0.9592	
		Race: Asian	N	62	83
			n (%)	2 (3.2)	1 (1.2)
			95% CI[a]	(0.00, 7.62)	(0.00, 3.55)
			Relative Risk (95% CI)[a]	2.68 (0.25, 28.87)	
			P-value	0.4169	
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.8989	
	Natural killer cell count decreased	Race: White	N	269	248
			n (%)	10 (3.7)	0
			95% CI[a]	(1.46, 5.98)	(0.00, 1.48)
			Relative Risk (95% CI)[a]	18.48 (1.08, 314.66)	
			P-value	0.0438	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Race: Black Or African American	N	25	26
			n (%)	0	0
		Race: Asian	N	62	83
			n (%)	0	0
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	NE	
	SARS-CoV-2 test positive	Race: White	N	269	248
			n (%)	14 (5.2)	11 (4.4)
			95% CI[a]	(2.55, 7.86)	(1.87, 7.00)
			Relative Risk (95% CI)[a]	1.17 (0.54, 2.54)	
			P-value	0.6843	
		Race: Black Or African American	N	25	26
			n (%)	1 (4.0)	2 (7.7)
			95% CI[a]	(0.00, 11.68)	(0.00, 17.93)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.52 (0.05, 5.38)	
			P-value	0.5834	
		Race: Asian	N	62	83
			n (%)	0	0
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.9298	
Nervous system disorders	Overall	Race: White	N	269	248
			n (%)	44 (16.4)	20 (8.1)
			95% CI[a]	(11.94, 20.78)	(4.68, 11.45)
			Relative Risk (95% CI)[a]	2.03 (1.23, 3.34)	
			P-value	0.0055	
		Race: Black Or African American	N	25	26
			n (%)	2 (8.0)	0
			95% CI[a]	(0.00, 18.63)	(0.00, 13.23)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	4.24 (0.20, 89.57)	
			P-value	0.3533	
		Race: Asian	N	62	83
			n (%)	9 (14.5)	7 (8.4)
			95% CI[a]	(5.75, 23.28)	(2.46, 14.41)
			Relative Risk (95% CI)[a]	1.72 (0.68, 4.37)	
			P-value	0.2531	
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.9278	
	Dizziness	Race: White	N	269	248
			n (%)	8 (3.0)	4 (1.6)
			95% CI[a]	(0.94, 5.00)	(0.05, 3.18)
			Relative Risk (95% CI)[a]	1.84 (0.56, 6.05)	
			P-value	0.3127	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Race: Black Or African American	N	25	26
			n (%)	0	0
		Race: Asian	N	62	83
			n (%)	2 (3.2)	0
			95% CI[a]	(0.00, 7.62)	(0.00, 4.35)
			Relative Risk (95% CI)[a]	5.39 (0.25, 117.39)	
			P-value	0.2841	
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.9469	
	Headache	Race: White	N	269	248
			n (%)	38 (14.1)	17 (6.9)
			95% CI[a]	(9.96, 18.29)	(3.71, 10.00)
			Relative Risk (95% CI)[a]	2.06 (1.19, 3.55)	
			P-value	0.0093	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Race: Black Or African American	N	25	26
			n (%)	2 (8.0)	0
			95% CI[a]	(0.00, 18.63)	(0.00, 13.23)
			Relative Risk (95% CI)[a]	4.24 (0.20, 89.57)	
			P-value	0.3533	
		Race: Asian	N	62	83
			n (%)	7 (11.3)	7 (8.4)
			95% CI[a]	(3.41, 19.17)	(2.46, 14.41)
			Relative Risk (95% CI)[a]	1.34 (0.50, 3.62)	
			P-value	0.5654	
		Race: Other	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.8658	
Skin and subcutaneous tissue disorders	Overall	Race: White	N	269	248
			n (%)	37 (13.8)	15 (6.0)
			95% CI[a]	(9.64, 17.87)	(3.08, 9.02)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.27 (1.28, 4.04)	
			P-value	0.0051	
		Race: Black Or African American	N	25	26
			n (%)	3 (12.0)	0
			95% CI[a]	(0.00, 24.74)	(0.00, 13.23)
			Relative Risk (95% CI)[a]	6.36 (0.34, 120.74)	
			P-value	0.2180	
		Race: Asian	N	62	83
			n (%)	17 (27.4)	6 (7.2)
			95% CI[a]	(16.32, 38.52)	(1.66, 12.80)
			Relative Risk (95% CI)[a]	3.79 (1.59, 9.06)	
			P-value	0.0027	
		Race: Other	N	6	8
			n (%)	4 (66.7)	2 (25.0)
			95% CI[a]	(28.95, 100.00)	(0.00, 55.01)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.67 (0.71, 10.05)	
			P-value	0.1474	
			Test for interaction[b]	0.2054	
	Acne	Race: White	N	269	248
			n (%)	26 (9.7)	5 (2.0)
			95% CI[a]	(6.13, 13.20)	(0.27, 3.77)
			Relative Risk (95% CI)[a]	4.79 (1.87, 12.29)	
			P-value	0.0011	
		Race: Black Or African American	N	25	26
			n (%)	2 (8.0)	0
			95% CI[a]	(0.00, 18.63)	(0.00, 13.23)
			Relative Risk (95% CI)[a]	4.24 (0.20, 89.57)	
			P-value	0.3533	
		Race: Asian	N	62	83
			n (%)	15 (24.2)	4 (4.8)
			95% CI[a]	(13.53, 34.85)	(0.21, 9.43)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	5.02 (1.75, 14.38)	
			P-value	0.0027	
		Race: Other	N	6	8
			n (%)	3 (50.0)	1 (12.5)
			95% CI[a]	(9.99, 90.01)	(0.00, 35.42)
			Relative Risk (95% CI)[a]	4.00 (0.54, 29.57)	
			P-value	0.1744	
			Test for interaction[b]	0.1873	
	Dermatitis atopic	Race: White	N	269	248
			n (%)	12 (4.5)	11 (4.4)
			95% CI[a]	(1.99, 6.93)	(1.87, 7.00)
			Relative Risk (95% CI)[a]	1.01 (0.45, 2.24)	
			P-value	0.9888	
		Race: Black Or African American	N	25	26
			n (%)	1 (4.0)	0
			95% CI[a]	(0.00, 11.68)	(0.00, 13.23)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.12 (0.07, 60.46)	
			P-value	0.6603	
		Race: Asian	N	62	83
			n (%)	3 (4.8)	2 (2.4)
			95% CI[a]	(0.00, 10.18)	(0.00, 5.71)
			Relative Risk (95% CI)[a]	2.01 (0.35, 11.66)	
			P-value	0.4372	
		Race: Other	N	6	8
			n (%)	1 (16.7)	1 (12.5)
			95% CI[a]	(0.00, 46.49)	(0.00, 35.42)
			Relative Risk (95% CI)[a]	1.33 (0.10, 17.28)	
			P-value	0.8258	
			Test for interaction[b]	0.9095	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	92 (52.0)	68 (34.9)
			95% CI[a]	(44.62, 59.34)	(28.18, 41.56)
			Relative Risk (95% CI)[a]	1.49 (1.17, 1.89)	
			P-value	0.0010	
		Region of enrollment: Europe	N	150	132
			n (%)	90 (60.0)	55 (41.7)
			95% CI[a]	(52.16, 67.84)	(33.26, 50.08)
			Relative Risk (95% CI)[a]	1.44 (1.13, 1.83)	
			P-value	0.0030	
		Region of enrollment: Asia	N	17	19
			n (%)	9 (52.9)	4 (21.1)
			95% CI[a]	(29.21, 76.67)	(2.72, 39.38)
			Relative Risk (95% CI)[a]	2.51 (0.94, 6.70)	
			P-value	0.0650	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Latin America	N	18	19
			n (%)	6 (33.3)	2 (10.5)
			95% CI[a]	(11.56, 55.11)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	3.17 (0.73, 13.70)	
			P-value	0.1230	
			Test for interaction[b]	0.8773	
Gastrointestinal disorders	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	39 (22.0)	6 (3.1)
			95% CI[a]	(15.93, 28.14)	(0.65, 5.50)
			Relative Risk (95% CI)[a]	7.16 (3.11, 16.51)	
			P-value	<.0001	
		Region of enrollment: Europe	N	150	132
			n (%)	30 (20.0)	5 (3.8)
			95% CI[a]	(13.60, 26.40)	(0.53, 7.04)
			Relative Risk (95% CI)[a]	5.28 (2.11, 13.21)	
			P-value	0.0004	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Asia	N	17	19
			n (%)	1 (5.9)	0
			95% CI[a]	(0.00, 17.07)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.29 (0.08, 64.21)	
			P-value	0.6252	
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.0039	
	Nausea	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	39 (22.0)	4 (2.1)
			95% CI[a]	(15.93, 28.14)	(0.06, 4.04)
			Relative Risk (95% CI)[a]	10.74 (3.92, 29.45)	
			P-value	<.0001	
		Region of enrollment: Europe	N	150	132
			n (%)	30 (20.0)	4 (3.0)
			95% CI[a]	(13.60, 26.40)	(0.11, 5.95)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	6.60 (2.39, 18.24)	
			P-value	0.0003	
		Region of enrollment: Asia	N	17	19
			n (%)	1 (5.9)	0
			95% CI[a]	(0.00, 17.07)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.29 (0.08, 64.21)	
			P-value	0.6252	
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.0019	
	Vomiting	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	7 (4.0)	3 (1.5)
			95% CI[a]	(1.08, 6.83)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	2.57 (0.68, 9.79)	
			P-value	0.1664	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Europe	N	150	132
			n (%)	4 (2.7)	3 (2.3)
			95% CI[a]	(0.09, 5.24)	(0.00, 4.82)
			Relative Risk (95% CI)[a]	1.17 (0.27, 5.15)	
			P-value	0.8322	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.8619	
General disorders and administration site conditions	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	6 (3.4)	2 (1.0)
			95% CI[a]	(0.72, 6.06)	(0.00, 2.44)
			Relative Risk (95% CI)[a]	3.31 (0.68, 16.16)	
			P-value	0.1399	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Europe	N	150	132
			n (%)	4 (2.7)	3 (2.3)
			95% CI[a]	(0.09, 5.24)	(0.00, 4.82)
			Relative Risk (95% CI)[a]	1.17 (0.27, 5.15)	
			P-value	0.8322	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.8540	
	Fatigue	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	6 (3.4)	2 (1.0)
			95% CI[a]	(0.72, 6.06)	(0.00, 2.44)
			Relative Risk (95% CI)[a]	3.31 (0.68, 16.16)	
			P-value	0.1399	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Europe	N	150	132
			n (%)	4 (2.7)	3 (2.3)
			95% CI[a]	(0.09, 5.24)	(0.00, 4.82)
			Relative Risk (95% CI)[a]	1.17 (0.27, 5.15)	
			P-value	0.8322	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.8540	
Infections and infestations	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	24 (13.6)	38 (19.5)
			95% CI[a]	(8.52, 18.60)	(13.93, 25.05)
			Relative Risk (95% CI)[a]	0.70 (0.44, 1.11)	
			P-value	0.1294	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Europe	N	150	132
			n (%)	41 (27.3)	36 (27.3)
			95% CI[a]	(20.20, 34.47)	(19.68, 34.87)
			Relative Risk (95% CI)[a]	1.00 (0.68, 1.47)	
			P-value	0.9909	
		Region of enrollment: Asia	N	17	19
			n (%)	2 (11.8)	1 (5.3)
			95% CI[a]	(0.00, 27.08)	(0.00, 15.30)
			Relative Risk (95% CI)[a]	2.24 (0.22, 22.51)	
			P-value	0.4948	
		Region of enrollment: Latin America	N	18	19
			n (%)	1 (5.6)	1 (5.3)
			95% CI[a]	(0.00, 16.14)	(0.00, 15.30)
			Relative Risk (95% CI)[a]	1.06 (0.07, 15.64)	
			P-value	0.9686	
			Test for interaction[b]	0.5531	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	COVID-19	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	4 (2.3)	4 (2.1)
			95% CI[a]	(0.07, 4.45)	(0.06, 4.04)
			Relative Risk (95% CI)[a]	1.10 (0.28, 4.34)	
			P-value	0.8899	
		Region of enrollment: Europe	N	150	132
			n (%)	11 (7.3)	7 (5.3)
			95% CI[a]	(3.16, 11.51)	(1.48, 9.13)
			Relative Risk (95% CI)[a]	1.38 (0.55, 3.46)	
			P-value	0.4890	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	1 (5.3)
			95% CI[a]	(0.00, 18.53)	(0.00, 15.30)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.51 (0.02, 14.40)	
			P-value	0.6952	
			Test for interaction[b]	0.9070	
	Conjunctivitis	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	4 (2.3)	18 (9.2)
			95% CI[a]	(0.07, 4.45)	(5.17, 13.29)
			Relative Risk (95% CI)[a]	0.24 (0.08, 0.71)	
			P-value	0.0095	
		Region of enrollment: Europe	N	150	132
			n (%)	3 (2.0)	16 (12.1)
			95% CI[a]	(0.00, 4.24)	(6.55, 17.69)
			Relative Risk (95% CI)[a]	0.17 (0.05, 0.55)	
			P-value	0.0035	
		Region of enrollment: Asia	N	17	19
			n (%)	1 (5.9)	1 (5.3)
			95% CI[a]	(0.00, 17.07)	(0.00, 15.30)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.12 (0.08, 16.52)	
			P-value	0.9355	
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.2628	
	Folliculitis	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	5 (2.8)	3 (1.5)
			95% CI[a]	(0.38, 5.27)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	1.84 (0.45, 7.57)	
			P-value	0.4006	
		Region of enrollment: Europe	N	150	132
			n (%)	5 (3.3)	0
			95% CI[a]	(0.46, 6.21)	(0.00, 2.76)
			Relative Risk (95% CI)[a]	8.83 (0.49, 160.17)	
			P-value	0.1406	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Asia	N	17	19
			n (%)	2 (11.8)	0
			95% CI[a]	(0.00, 27.08)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	4.59 (0.22, 94.96)	
			P-value	0.3244	
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.7124	
	Herpes simplex	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	3 (1.7)	1 (0.5)
			95% CI[a]	(0.00, 3.60)	(0.00, 1.52)
			Relative Risk (95% CI)[a]	3.31 (0.35, 31.48)	
			P-value	0.2986	
		Region of enrollment: Europe	N	150	132
			n (%)	9 (6.0)	4 (3.0)
			95% CI[a]	(2.20, 9.80)	(0.11, 5.95)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.98 (0.62, 6.28)	
			P-value	0.2461	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9031	
	Nasopharyngitis	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	2 (1.1)	4 (2.1)
			95% CI[a]	(0.00, 2.69)	(0.06, 4.04)
			Relative Risk (95% CI)[a]	0.55 (0.10, 2.97)	
			P-value	0.4880	
		Region of enrollment: Europe	N	150	132
			n (%)	11 (7.3)	8 (6.1)
			95% CI[a]	(3.16, 11.51)	(1.99, 10.13)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.21 (0.50, 2.92)	
			P-value	0.6712	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	1 (5.6)	0
			95% CI[a]	(0.00, 16.14)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.17 (0.08, 60.76)	
			P-value	0.6494	
			Test for interaction[b]	0.8600	
	Oral herpes	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	1 (0.6)	5 (2.6)
			95% CI[a]	(0.00, 1.67)	(0.35, 4.78)
			Relative Risk (95% CI)[a]	0.22 (0.03, 1.87)	
			P-value	0.1654	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Europe	N	150	132
			n (%)	8 (5.3)	10 (7.6)
			95% CI[a]	(1.74, 8.93)	(3.06, 12.09)
			Relative Risk (95% CI)[a]	0.70 (0.29, 1.73)	
			P-value	0.4446	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9522	
	Upper respiratory tract infection	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	7 (4.0)	6 (3.1)
			95% CI[a]	(1.08, 6.83)	(0.65, 5.50)
			Relative Risk (95% CI)[a]	1.29 (0.44, 3.75)	
			P-value	0.6461	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Europe	N	150	132
			n (%)	3 (2.0)	3 (2.3)
			95% CI[a]	(0.00, 4.24)	(0.00, 4.82)
			Relative Risk (95% CI)[a]	0.88 (0.18, 4.29)	
			P-value	0.8742	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9776	
Investigations	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	12 (6.8)	13 (6.7)
			95% CI[a]	(3.08, 10.48)	(3.17, 10.17)
			Relative Risk (95% CI)[a]	1.02 (0.48, 2.17)	
			P-value	0.9653	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Europe	N	150	132
			n (%)	23 (15.3)	11 (8.3)
			95% CI[a]	(9.57, 21.10)	(3.62, 13.05)
			Relative Risk (95% CI)[a]	1.84 (0.93, 3.63)	
			P-value	0.0785	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	3 (16.7)	2 (10.5)
			95% CI[a]	(0.00, 33.88)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	1.58 (0.30, 8.40)	
			P-value	0.5894	
			Test for interaction[b]	0.4656	
	Blood creatine phosphokinase increased	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	8 (4.5)	8 (4.1)
			95% CI[a]	(1.46, 7.58)	(1.32, 6.89)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.10 (0.42, 2.87)	
			P-value	0.8430	
		Region of enrollment: Europe	N	150	132
			n (%)	4 (2.7)	4 (3.0)
			95% CI[a]	(0.09, 5.24)	(0.11, 5.95)
			Relative Risk (95% CI)[a]	0.88 (0.22, 3.45)	
			P-value	0.8545	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	2 (11.1)	1 (5.3)
			95% CI[a]	(0.00, 25.63)	(0.00, 15.30)
			Relative Risk (95% CI)[a]	2.11 (0.21, 21.32)	
			P-value	0.5265	
			Test for interaction[b]	0.9243	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Natural killer cell count decreased	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	0	0
		Region of enrollment: Europe	N	150	132
			n (%)	10 (6.7)	0
			95% CI[a]	(2.67, 10.66)	(0.00, 2.76)
			Relative Risk (95% CI)[a]	17.67 (1.04, 299.56)	
			P-value	0.0468	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	NE	
	SARS-CoV-2 test positive	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	4 (2.3)	5 (2.6)
			95% CI[a]	(0.07, 4.45)	(0.35, 4.78)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.88 (0.24, 3.23)	
			P-value	0.8489	
		Region of enrollment: Europe	N	150	132
			n (%)	10 (6.7)	7 (5.3)
			95% CI[a]	(2.67, 10.66)	(1.48, 9.13)
			Relative Risk (95% CI)[a]	1.26 (0.49, 3.21)	
			P-value	0.6322	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	1 (5.6)	1 (5.3)
			95% CI[a]	(0.00, 16.14)	(0.00, 15.30)
			Relative Risk (95% CI)[a]	1.06 (0.07, 15.64)	
			P-value	0.9686	
			Test for interaction[b]	0.9659	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Nervous system disorders	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	24 (13.6)	13 (6.7)
			95% CI[a]	(8.52, 18.60)	(3.17, 10.17)
			Relative Risk (95% CI)[a]	2.03 (1.07, 3.87)	
			P-value	0.0306	
		Region of enrollment: Europe	N	150	132
			n (%)	27 (18.0)	12 (9.1)
			95% CI[a]	(11.85, 24.15)	(4.19, 14.00)
			Relative Risk (95% CI)[a]	1.98 (1.05, 3.75)	
			P-value	0.0360	
		Region of enrollment: Asia	N	17	19
			n (%)	2 (11.8)	2 (10.5)
			95% CI[a]	(0.00, 27.08)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	1.12 (0.18, 7.09)	
			P-value	0.9061	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Latin America	N	18	19
			n (%)	2 (11.1)	0
			95% CI[a]	(0.00, 25.63)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	4.33 (0.21, 89.87)	
			P-value	0.3432	
			Test for interaction[b]	0.9048	
	Dizziness	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	4 (2.3)	1 (0.5)
			95% CI[a]	(0.07, 4.45)	(0.00, 1.52)
			Relative Risk (95% CI)[a]	4.41 (0.50, 39.06)	
			P-value	0.1828	
		Region of enrollment: Europe	N	150	132
			n (%)	6 (4.0)	3 (2.3)
			95% CI[a]	(0.86, 7.14)	(0.00, 4.82)
			Relative Risk (95% CI)[a]	1.76 (0.45, 6.90)	
			P-value	0.4173	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9848	
	Headache	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	21 (11.9)	12 (6.2)
			95% CI[a]	(7.10, 16.63)	(2.78, 9.53)
			Relative Risk (95% CI)[a]	1.93 (0.98, 3.80)	
			P-value	0.0583	
		Region of enrollment: Europe	N	150	132
			n (%)	22 (14.7)	10 (7.6)
			95% CI[a]	(9.01, 20.33)	(3.06, 12.09)
			Relative Risk (95% CI)[a]	1.94 (0.95, 3.94)	
			P-value	0.0682	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Asia	N	17	19
			n (%)	2 (11.8)	2 (10.5)
			95% CI[a]	(0.00, 27.08)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	1.12 (0.18, 7.09)	
			P-value	0.9061	
		Region of enrollment: Latin America	N	18	19
			n (%)	2 (11.1)	0
			95% CI[a]	(0.00, 25.63)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	4.33 (0.21, 89.87)	
			P-value	0.3432	
			Test for interaction[b]	0.9443	
Skin and subcutaneous tissue disorders	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	34 (19.2)	14 (7.2)
			95% CI[a]	(13.41, 25.01)	(3.56, 10.80)
			Relative Risk (95% CI)[a]	2.68 (1.49, 4.82)	
			P-value	0.0010	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Europe	N	150	132
			n (%)	21 (14.0)	7 (5.3)
			95% CI[a]	(8.45, 19.55)	(1.48, 9.13)
			Relative Risk (95% CI)[a]	2.64 (1.16, 6.01)	
			P-value	0.0208	
		Region of enrollment: Asia	N	17	19
			n (%)	5 (29.4)	2 (10.5)
			95% CI[a]	(7.75, 51.07)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	2.79 (0.62, 12.57)	
			P-value	0.1805	
		Region of enrollment: Latin America	N	18	19
			n (%)	1 (5.6)	0
			95% CI[a]	(0.00, 16.14)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.17 (0.08, 60.76)	
			P-value	0.6494	
			Test for interaction[b]	0.4840	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Acne	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	29 (16.4)	7 (3.6)
			95% CI[a]	(10.93, 21.84)	(0.98, 6.20)
			Relative Risk (95% CI)[a]	4.56 (2.05, 10.16)	
			P-value	0.0002	
		Region of enrollment: Europe	N	150	132
			n (%)	13 (8.7)	1 (0.8)
			95% CI[a]	(4.16, 13.17)	(0.00, 2.24)
			Relative Risk (95% CI)[a]	11.44 (1.52, 86.28)	
			P-value	0.0181	
		Region of enrollment: Asia	N	17	19
			n (%)	4 (23.5)	2 (10.5)
			95% CI[a]	(3.37, 43.69)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	2.24 (0.47, 10.70)	
			P-value	0.3141	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.1633	
	Dermatitis atopic	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	5 (2.8)	8 (4.1)
			95% CI[a]	(0.38, 5.27)	(1.32, 6.89)
			Relative Risk (95% CI)[a]	0.69 (0.23, 2.07)	
			P-value	0.5056	
		Region of enrollment: Europe	N	150	132
			n (%)	9 (6.0)	6 (4.5)
			95% CI[a]	(2.20, 9.80)	(0.99, 8.10)
			Relative Risk (95% CI)[a]	1.32 (0.48, 3.61)	
			P-value	0.5886	
		Region of enrollment: Asia	N	17	19
			n (%)	2 (11.8)	0
			95% CI[a]	(0.00, 27.08)	(0.00, 17.65)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	4.59 (0.22, 94.96)	
			P-value	0.3244	
		Region of enrollment: Latin America	N	18	19
			n (%)	1 (5.6)	0
			95% CI[a]	(0.00, 16.14)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.17 (0.08, 60.76)	
			P-value	0.6494	
			Test for interaction[b]	0.5650	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	121 (56.0)	76 (34.5)
			95% CI[a]	(49.40, 62.64)	(28.26, 40.83)
			Relative Risk (95% CI)[a]	1.62 (1.31, 2.01)	
			P-value	<.0001	
		Baseline disease severity: Severe	N	146	145
			n (%)	76 (52.1)	53 (36.6)
			95% CI[a]	(43.95, 60.16)	(28.71, 44.39)
			Relative Risk (95% CI)[a]	1.42 (1.09, 1.86)	
			P-value	0.0089	
			Test for interaction[b]	0.4029	
Gastrointestinal disorders	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	45 (20.8)	7 (3.2)
			95% CI[a]	(15.42, 26.25)	(0.86, 5.50)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	6.55 (3.02, 14.20)	
			P-value	<.0001	
		Baseline disease severity: Severe	N	146	145
			n (%)	25 (17.1)	4 (2.8)
			95% CI[a]	(11.01, 23.23)	(0.09, 5.42)
			Relative Risk (95% CI)[a]	6.21 (2.22, 17.39)	
			P-value	0.0005	
			Test for interaction[b]	0.4477	
	Nausea	Baseline disease severity: Moderate	N	216	220
			n (%)	45 (20.8)	7 (3.2)
			95% CI[a]	(15.42, 26.25)	(0.86, 5.50)
			Relative Risk (95% CI)[a]	6.55 (3.02, 14.20)	
			P-value	<.0001	
		Baseline disease severity: Severe	N	146	145
			n (%)	25 (17.1)	1 (0.7)
			95% CI[a]	(11.01, 23.23)	(0.00, 2.04)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	24.83 (3.41, 180.82)	
			P-value	0.0015	
			Test for interaction[b]	0.7016	
	Vomiting	Baseline disease severity: Moderate	N	216	220
			n (%)	5 (2.3)	2 (0.9)
			95% CI[a]	(0.31, 4.32)	(0.00, 2.16)
			Relative Risk (95% CI)[a]	2.55 (0.50, 12.98)	
			P-value	0.2608	
		Baseline disease severity: Severe	N	146	145
			n (%)	6 (4.1)	4 (2.8)
			95% CI[a]	(0.89, 7.33)	(0.09, 5.42)
			Relative Risk (95% CI)[a]	1.49 (0.43, 5.17)	
			P-value	0.5300	
			Test for interaction[b]	0.9906	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
General disorders and administration site conditions	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	6 (2.8)	3 (1.4)
			95% CI[a]	(0.59, 4.97)	(0.00, 2.90)
			Relative Risk (95% CI)[a]	2.04 (0.52, 8.04)	
			P-value	0.3098	
		Baseline disease severity: Severe	N	146	145
			n (%)	4 (2.7)	2 (1.4)
			95% CI[a]	(0.09, 5.39)	(0.00, 3.28)
			Relative Risk (95% CI)[a]	1.99 (0.37, 10.68)	
			P-value	0.4238	
			Test for interaction[b]	0.9801	
	Fatigue	Baseline disease severity: Moderate	N	216	220
			n (%)	6 (2.8)	3 (1.4)
			95% CI[a]	(0.59, 4.97)	(0.00, 2.90)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.04 (0.52, 8.04)	
			P-value	0.3098	
		Baseline disease severity: Severe	N	146	145
			n (%)	4 (2.7)	2 (1.4)
			95% CI[a]	(0.09, 5.39)	(0.00, 3.28)
			Relative Risk (95% CI)[a]	1.99 (0.37, 10.68)	
			P-value	0.4238	
			Test for interaction[b]	0.9801	
Infections and infestations	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	44 (20.4)	45 (20.5)
			95% CI[a]	(15.00, 25.74)	(15.12, 25.78)
			Relative Risk (95% CI)[a]	1.00 (0.69, 1.44)	
			P-value	0.9826	
		Baseline disease severity: Severe	N	146	145
			n (%)	24 (16.4)	31 (21.4)
			95% CI[a]	(10.43, 22.45)	(14.71, 28.05)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.77 (0.48, 1.24)	
			P-value	0.2840	
			Test for interaction[b]	0.4225	
	COVID-19	Baseline disease severity: Moderate	N	216	220
			n (%)	8 (3.7)	7 (3.2)
			95% CI[a]	(1.19, 6.22)	(0.86, 5.50)
			Relative Risk (95% CI)[a]	1.16 (0.43, 3.15)	
			P-value	0.7652	
		Baseline disease severity: Severe	N	146	145
			n (%)	7 (4.8)	5 (3.4)
			95% CI[a]	(1.33, 8.26)	(0.48, 6.42)
			Relative Risk (95% CI)[a]	1.39 (0.45, 4.28)	
			P-value	0.5656	
			Test for interaction[b]	0.7757	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Conjunctivitis	Baseline disease severity: Moderate	N	216	220
			n (%)	3 (1.4)	23 (10.5)
			95% CI[a]	(0.00, 2.95)	(6.41, 14.50)
			Relative Risk (95% CI)[a]	0.13 (0.04, 0.44)	
			P-value	0.0009	
		Baseline disease severity: Severe	N	146	145
			n (%)	5 (3.4)	12 (8.3)
			95% CI[a]	(0.47, 6.37)	(3.79, 12.76)
			Relative Risk (95% CI)[a]	0.41 (0.15, 1.14)	
			P-value	0.0893	
			Test for interaction[b]	0.2401	
	Folliculitis	Baseline disease severity: Moderate	N	216	220
			n (%)	9 (4.2)	1 (0.5)
			95% CI[a]	(1.50, 6.83)	(0.00, 1.34)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	9.17 (1.17, 71.74)	
			P-value	0.0348	
		Baseline disease severity: Severe	N	146	145
			n (%)	3 (2.1)	2 (1.4)
			95% CI[a]	(0.00, 4.36)	(0.00, 3.28)
			Relative Risk (95% CI)[a]	1.49 (0.25, 8.78)	
			P-value	0.6597	
			Test for interaction[b]	0.1476	
	Herpes simplex	Baseline disease severity: Moderate	N	216	220
			n (%)	7 (3.2)	1 (0.5)
			95% CI[a]	(0.88, 5.60)	(0.00, 1.34)
			Relative Risk (95% CI)[a]	7.13 (0.88, 57.46)	
			P-value	0.0651	
		Baseline disease severity: Severe	N	146	145
			n (%)	5 (3.4)	4 (2.8)
			95% CI[a]	(0.47, 6.37)	(0.09, 5.42)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.24 (0.34, 4.53)	
			P-value	0.7433	
			Test for interaction[b]	0.3854	
	Nasopharyngitis	Baseline disease severity: Moderate	N	216	220
			n (%)	9 (4.2)	10 (4.5)
			95% CI[a]	(1.50, 6.83)	(1.79, 7.30)
			Relative Risk (95% CI)[a]	0.92 (0.38, 2.21)	
			P-value	0.8465	
		Baseline disease severity: Severe	N	146	145
			n (%)	5 (3.4)	2 (1.4)
			95% CI[a]	(0.47, 6.37)	(0.00, 3.28)
			Relative Risk (95% CI)[a]	2.48 (0.49, 12.59)	
			P-value	0.2723	
			Test for interaction[b]	0.3651	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Oral herpes	Baseline disease severity: Moderate	N	216	220
			n (%)	5 (2.3)	7 (3.2)
			95% CI[a]	(0.31, 4.32)	(0.86, 5.50)
			Relative Risk (95% CI)[a]	0.73 (0.23, 2.26)	
			P-value	0.5818	
		Baseline disease severity: Severe	N	146	145
			n (%)	4 (2.7)	8 (5.5)
			95% CI[a]	(0.09, 5.39)	(1.80, 9.23)
			Relative Risk (95% CI)[a]	0.50 (0.15, 1.61)	
			P-value	0.2442	
			Test for interaction[b]	0.4927	
	Upper respiratory tract infection	Baseline disease severity: Moderate	N	216	220
			n (%)	9 (4.2)	5 (2.3)
			95% CI[a]	(1.50, 6.83)	(0.30, 4.24)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.83 (0.62, 5.38)	
			P-value	0.2700	
		Baseline disease severity: Severe	N	146	145
			n (%)	1 (0.7)	4 (2.8)
			95% CI[a]	(0.00, 2.02)	(0.09, 5.42)
			Relative Risk (95% CI)[a]	0.25 (0.03, 2.19)	
			P-value	0.2102	
			Test for interaction[b]	0.0828	
Investigations	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	24 (11.1)	15 (6.8)
			95% CI[a]	(6.92, 15.30)	(3.49, 10.15)
			Relative Risk (95% CI)[a]	1.63 (0.88, 3.02)	
			P-value	0.1209	
		Baseline disease severity: Severe	N	146	145
			n (%)	14 (9.6)	11 (7.6)
			95% CI[a]	(4.81, 14.37)	(3.28, 11.90)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.26 (0.59, 2.69)	
			P-value	0.5433	
			Test for interaction[b]	0.5906	
	Blood creatine phosphokinase increased	Baseline disease severity: Moderate	N	216	220
			n (%)	9 (4.2)	7 (3.2)
			95% CI[a]	(1.50, 6.83)	(0.86, 5.50)
			Relative Risk (95% CI)[a]	1.31 (0.50, 3.45)	
			P-value	0.5857	
		Baseline disease severity: Severe	N	146	145
			n (%)	5 (3.4)	6 (4.1)
			95% CI[a]	(0.47, 6.37)	(0.90, 7.38)
			Relative Risk (95% CI)[a]	0.83 (0.26, 2.65)	
			P-value	0.7501	
			Test for interaction[b]	0.5547	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Natural killer cell count decreased	Baseline disease severity: Moderate	N	216	220
			n (%)	6 (2.8)	0
			95% CI[a]	(0.59, 4.97)	(0.00, 1.66)
			Relative Risk (95% CI)[a]	12.25 (0.69, 217.98)	
			P-value	0.0880	
		Baseline disease severity: Severe	N	146	145
			n (%)	4 (2.7)	0
			95% CI[a]	(0.09, 5.39)	(0.00, 2.51)
			Relative Risk (95% CI)[a]	7.97 (0.43, 149.45)	
			P-value	0.1651	
			Test for interaction[b]	0.9343	
	SARS-CoV-2 test positive	Baseline disease severity: Moderate	N	216	220
			n (%)	10 (4.6)	8 (3.6)
			95% CI[a]	(1.83, 7.43)	(1.16, 6.11)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.27 (0.51, 3.16)	
			P-value	0.6032	
		Baseline disease severity: Severe	N	146	145
			n (%)	5 (3.4)	5 (3.4)
			95% CI[a]	(0.47, 6.37)	(0.48, 6.42)
			Relative Risk (95% CI)[a]	0.99 (0.29, 3.36)	
			P-value	0.9912	
			Test for interaction[b]	0.7215	
Nervous system disorders	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	30 (13.9)	18 (8.2)
			95% CI[a]	(9.28, 18.50)	(4.56, 11.80)
			Relative Risk (95% CI)[a]	1.70 (0.98, 2.95)	
			P-value	0.0609	
		Baseline disease severity: Severe	N	146	145
			n (%)	25 (17.1)	9 (6.2)
			95% CI[a]	(11.01, 23.23)	(2.28, 10.13)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.76 (1.33, 5.70)	
			P-value	0.0062	
			Test for interaction[b]	0.2787	
	Dizziness	Baseline disease severity: Moderate	N	216	220
			n (%)	4 (1.9)	3 (1.4)
			95% CI[a]	(0.05, 3.65)	(0.00, 2.90)
			Relative Risk (95% CI)[a]	1.36 (0.31, 6.00)	
			P-value	0.6863	
		Baseline disease severity: Severe	N	146	145
			n (%)	6 (4.1)	1 (0.7)
			95% CI[a]	(0.89, 7.33)	(0.00, 2.04)
			Relative Risk (95% CI)[a]	5.96 (0.73, 48.88)	
			P-value	0.0965	
			Test for interaction[b]	0.1749	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Headache	Baseline disease severity: Moderate	N	216	220
			n (%)	27 (12.5)	15 (6.8)
			95% CI[a]	(8.09, 16.91)	(3.49, 10.15)
			Relative Risk (95% CI)[a]	1.83 (1.00, 3.35)	
			P-value	0.0487	
		Baseline disease severity: Severe	N	146	145
			n (%)	20 (13.7)	9 (6.2)
			95% CI[a]	(8.12, 19.28)	(2.28, 10.13)
			Relative Risk (95% CI)[a]	2.21 (1.04, 4.68)	
			P-value	0.0392	
			Test for interaction[b]	0.6865	
Skin and subcutaneous tissue disorders	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	34 (15.7)	9 (4.1)
			95% CI[a]	(10.88, 20.60)	(1.47, 6.71)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	3.85 (1.89, 7.83)	
			P-value	0.0002	
		Baseline disease severity: Severe	N	146	145
			n (%)	27 (18.5)	14 (9.7)
			95% CI[a]	(12.20, 24.79)	(4.85, 14.46)
			Relative Risk (95% CI)[a]	1.92 (1.05, 3.50)	
			P-value	0.0347	
			Test for interaction[b]	0.6464	
	Acne	Baseline disease severity: Moderate	N	216	220
			n (%)	29 (13.4)	2 (0.9)
			95% CI[a]	(8.88, 17.97)	(0.00, 2.16)
			Relative Risk (95% CI)[a]	14.77 (3.57, 61.13)	
			P-value	0.0002	
		Baseline disease severity: Severe	N	146	145
			n (%)	17 (11.6)	8 (5.5)
			95% CI[a]	(6.44, 16.85)	(1.80, 9.23)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.11 (0.94, 4.74)	
			P-value	0.0701	
			Test for interaction[b]	0.1346	
	Dermatitis atopic	Baseline disease severity: Moderate	N	216	220
			n (%)	7 (3.2)	8 (3.6)
			95% CI[a]	(0.88, 5.60)	(1.16, 6.11)
			Relative Risk (95% CI)[a]	0.89 (0.33, 2.41)	
			P-value	0.8208	
		Baseline disease severity: Severe	N	146	145
			n (%)	10 (6.8)	6 (4.1)
			95% CI[a]	(2.75, 10.95)	(0.90, 7.38)
			Relative Risk (95% CI)[a]	1.66 (0.62, 4.44)	
			P-value	0.3163	
			Test for interaction[b]	0.3289	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	21 (52.5)	14 (27.5)
			95% CI[a]	(37.02, 67.98)	(15.20, 39.70)
			Relative Risk (95% CI)[a]	1.91 (1.12, 3.26)	
			P-value	0.0175	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	176 (54.7)	115 (36.6)
			95% CI[a]	(49.22, 60.10)	(31.30, 41.95)
			Relative Risk (95% CI)[a]	1.49 (1.25, 1.78)	
			P-value	<.0001	
			Test for interaction[b]	0.6600	
Gastrointestinal disorders	Overall	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	5 (12.5)	3 (5.9)
			95% CI[a]	(2.25, 22.75)	(0.00, 12.34)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.12 (0.54, 8.36)	
			P-value	0.2809	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	65 (20.2)	8 (2.5)
			95% CI[a]	(15.80, 24.57)	(0.80, 4.29)
			Relative Risk (95% CI)[a]	7.92 (3.87, 16.24)	
			P-value	<.0001	
			Test for interaction[b]	0.0922	
	Nausea	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	5 (12.5)	2 (3.9)
			95% CI[a]	(2.25, 22.75)	(0.00, 9.25)
			Relative Risk (95% CI)[a]	3.19 (0.65, 15.58)	
			P-value	0.1522	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	65 (20.2)	6 (1.9)
			95% CI[a]	(15.80, 24.57)	(0.40, 3.43)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	10.56 (4.64, 24.03)	
			P-value	<.0001	
			Test for interaction[b]	0.1189	
	Vomiting	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	1 (2.5)	1 (2.0)
			95% CI[a]	(0.00, 7.34)	(0.00, 5.77)
			Relative Risk (95% CI)[a]	1.27 (0.08, 19.76)	
			P-value	0.8621	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	10 (3.1)	5 (1.6)
			95% CI[a]	(1.21, 5.00)	(0.21, 2.98)
			Relative Risk (95% CI)[a]	1.95 (0.67, 5.64)	
			P-value	0.2177	
			Test for interaction[b]	0.7718	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
General disorders and administration site conditions	Overall	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	2 (5.0)	1 (2.0)
			95% CI[a]	(0.00, 11.75)	(0.00, 5.77)
			Relative Risk (95% CI)[a]	2.55 (0.24, 27.13)	
			P-value	0.4378	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	8 (2.5)	4 (1.3)
			95% CI[a]	(0.78, 4.18)	(0.03, 2.51)
			Relative Risk (95% CI)[a]	1.95 (0.59, 6.41)	
			P-value	0.2713	
			Test for interaction[b]	0.6542	
	Fatigue	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	2 (5.0)	1 (2.0)
			95% CI[a]	(0.00, 11.75)	(0.00, 5.77)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.55 (0.24, 27.13)	
			P-value	0.4378	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	8 (2.5)	4 (1.3)
			95% CI[a]	(0.78, 4.18)	(0.03, 2.51)
			Relative Risk (95% CI)[a]	1.95 (0.59, 6.41)	
			P-value	0.2713	
			Test for interaction[b]	0.6542	
Infections and infestations	Overall	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	10 (25.0)	7 (13.7)
			95% CI[a]	(11.58, 38.42)	(4.28, 23.17)
			Relative Risk (95% CI)[a]	1.82 (0.76, 4.36)	
			P-value	0.1781	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	58 (18.0)	69 (22.0)
			95% CI[a]	(13.82, 22.21)	(17.39, 26.55)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.82 (0.60, 1.12)	
			P-value	0.2126	
			Test for interaction[b]	0.0968	
	COVID-19	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	3 (7.5)	1 (2.0)
			95% CI[a]	(0.00, 15.66)	(0.00, 5.77)
			Relative Risk (95% CI)[a]	3.82 (0.41, 35.39)	
			P-value	0.2373	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	12 (3.7)	11 (3.5)
			95% CI[a]	(1.66, 5.80)	(1.47, 5.54)
			Relative Risk (95% CI)[a]	1.06 (0.48, 2.38)	
			P-value	0.8800	
			Test for interaction[b]	0.2785	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Conjunctivitis	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	1 (2.5)	2 (3.9)
			95% CI[a]	(0.00, 7.34)	(0.00, 9.25)
			Relative Risk (95% CI)[a]	0.64 (0.06, 6.78)	
			P-value	0.7090	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	7 (2.2)	33 (10.5)
			95% CI[a]	(0.58, 3.77)	(7.12, 13.90)
			Relative Risk (95% CI)[a]	0.21 (0.09, 0.46)	
			P-value	0.0001	
			Test for interaction[b]	0.0867	
	Folliculitis	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	1 (2.5)	0
			95% CI[a]	(0.00, 7.34)	(0.00, 6.98)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.58 (0.09, 74.84)	
			P-value	0.5822	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	11 (3.4)	3 (1.0)
			95% CI[a]	(1.43, 5.40)	(0.00, 2.03)
			Relative Risk (95% CI)[a]	3.58 (1.01, 12.70)	
			P-value	0.0487	
			Test for interaction[b]	0.7582	
	Herpes simplex	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	1 (2.5)	0
			95% CI[a]	(0.00, 7.34)	(0.00, 6.98)
			Relative Risk (95% CI)[a]	2.58 (0.09, 74.84)	
			P-value	0.5822	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	11 (3.4)	5 (1.6)
			95% CI[a]	(1.43, 5.40)	(0.21, 2.98)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.15 (0.75, 6.10)	
			P-value	0.1525	
			Test for interaction[b]	0.9205	
	Nasopharyngitis	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	1 (2.5)	0
			95% CI[a]	(0.00, 7.34)	(0.00, 6.98)
			Relative Risk (95% CI)[a]	2.58 (0.09, 74.84)	
			P-value	0.5822	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	13 (4.0)	12 (3.8)
			95% CI[a]	(1.89, 6.19)	(1.70, 5.94)
			Relative Risk (95% CI)[a]	1.06 (0.49, 2.28)	
			P-value	0.8888	
			Test for interaction[b]	0.6865	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Oral herpes	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	4 (10.0)	4 (7.8)
			95% CI[a]	(0.70, 19.30)	(0.46, 15.22)
			Relative Risk (95% CI)[a]	1.27 (0.34, 4.79)	
			P-value	0.7188	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	5 (1.6)	11 (3.5)
			95% CI[a]	(0.20, 2.90)	(1.47, 5.54)
			Relative Risk (95% CI)[a]	0.44 (0.16, 1.26)	
			P-value	0.1272	
			Test for interaction[b]	0.5199	
	Upper respiratory tract infection	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	1 (2.5)	1 (2.0)
			95% CI[a]	(0.00, 7.34)	(0.00, 5.77)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.27 (0.08, 19.76)	
			P-value	0.8621	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	9 (2.8)	8 (2.5)
			95% CI[a]	(0.99, 4.60)	(0.80, 4.29)
			Relative Risk (95% CI)[a]	1.10 (0.43, 2.81)	
			P-value	0.8468	
			Test for interaction[b]	0.9317	
Investigations	Overall	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	3 (7.5)	3 (5.9)
			95% CI[a]	(0.00, 15.66)	(0.00, 12.34)
			Relative Risk (95% CI)[a]	1.27 (0.27, 5.98)	
			P-value	0.7581	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	35 (10.9)	23 (7.3)
			95% CI[a]	(7.47, 14.27)	(4.44, 10.21)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.48 (0.90, 2.45)	
			P-value	0.1238	
			Test for interaction[b]	0.7281	
	Blood creatine phosphokinase increased	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	0	2 (3.9)
			95% CI[a]	(0.00, 8.81)	(0.00, 9.25)
			Relative Risk (95% CI)[a]	0.31 (0.01, 6.79)	
			P-value	0.4608	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	14 (4.3)	11 (3.5)
			95% CI[a]	(2.12, 6.58)	(1.47, 5.54)
			Relative Risk (95% CI)[a]	1.24 (0.57, 2.69)	
			P-value	0.5845	
			Test for interaction[b]	0.3250	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Natural killer cell count decreased	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	0	0
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	10 (3.1)	0
			95% CI[a]	(1.21, 5.00)	(0.00, 1.17)
			Relative Risk (95% CI)[a]	19.53 (1.15, 333.01)	
			P-value	0.0400	
			Test for interaction[b]	NE	
	SARS-CoV-2 test positive	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	3 (7.5)	1 (2.0)
			95% CI[a]	(0.00, 15.66)	(0.00, 5.77)
			Relative Risk (95% CI)[a]	3.82 (0.41, 35.39)	
			P-value	0.2373	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	12 (3.7)	12 (3.8)
			95% CI[a]	(1.66, 5.80)	(1.70, 5.94)
			Relative Risk (95% CI)[a]	0.98 (0.44, 2.14)	
			P-value	0.9499	
			Test for interaction[b]	0.2520	
Nervous system disorders	Overall	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	7 (17.5)	1 (2.0)
			95% CI[a]	(5.72, 29.28)	(0.00, 5.77)
			Relative Risk (95% CI)[a]	8.92 (1.14, 69.61)	
			P-value	0.0367	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	48 (14.9)	26 (8.3)
			95% CI[a]	(11.02, 18.80)	(5.23, 11.33)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.80 (1.15, 2.83)	
			P-value	0.0107	
			Test for interaction[b]	0.2271	
	Dizziness	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	3 (7.5)	0
			95% CI[a]	(0.00, 15.66)	(0.00, 6.98)
			Relative Risk (95% CI)[a]	7.73 (0.40, 149.86)	
			P-value	0.1766	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	7 (2.2)	4 (1.3)
			95% CI[a]	(0.58, 3.77)	(0.03, 2.51)
			Relative Risk (95% CI)[a]	1.71 (0.50, 5.77)	
			P-value	0.3900	
			Test for interaction[b]	0.2210	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Headache	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	4 (10.0)	1 (2.0)
			95% CI[a]	(0.70, 19.30)	(0.00, 5.77)
			Relative Risk (95% CI)[a]	5.10 (0.59, 43.86)	
			P-value	0.1378	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	43 (13.4)	23 (7.3)
			95% CI[a]	(9.64, 17.07)	(4.44, 10.21)
			Relative Risk (95% CI)[a]	1.82 (1.13, 2.95)	
			P-value	0.0146	
			Test for interaction[b]	0.7697	
Skin and subcutaneous tissue disorders	Overall	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	7 (17.5)	2 (3.9)
			95% CI[a]	(5.72, 29.28)	(0.00, 9.25)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	4.46 (0.98, 20.32)	
			P-value	0.0531	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	54 (16.8)	21 (6.7)
			95% CI[a]	(12.69, 20.85)	(3.92, 9.45)
			Relative Risk (95% CI)[a]	2.51 (1.55, 4.05)	
			P-value	0.0002	
			Test for interaction[b]	0.6485	
	Acne	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	4 (10.0)	0
			95% CI[a]	(0.70, 19.30)	(0.00, 6.98)
			Relative Risk (95% CI)[a]	10.30 (0.56, 189.22)	
			P-value	0.1163	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	42 (13.0)	10 (3.2)
			95% CI[a]	(9.37, 16.72)	(1.24, 5.13)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	4.10 (2.09, 8.02)	
			P-value	<.0001	
			Test for interaction[b]	0.8429	
	Dermatitis atopic	Previous cyclosporine exposure: Cyclosporine Exposed	N	40	51
			n (%)	5 (12.5)	2 (3.9)
			95% CI[a]	(2.25, 22.75)	(0.00, 9.25)
			Relative Risk (95% CI)[a]	3.19 (0.65, 15.58)	
			P-value	0.1522	
		Previous cyclosporine exposure: Cyclosporine Naive	N	322	314
			n (%)	12 (3.7)	12 (3.8)
			95% CI[a]	(1.66, 5.80)	(1.70, 5.94)
			Relative Risk (95% CI)[a]	0.98 (0.44, 2.14)	
			P-value	0.9499	
			Test for interaction[b]	0.1643	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	Weight(kg): <70	N	132	136
			n (%)	75 (56.8)	50 (36.8)
			95% CI[a]	(48.37, 65.27)	(28.66, 44.87)
			Relative Risk (95% CI)[a]	1.55 (1.18, 2.02)	
			P-value	0.0013	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	105 (53.6)	68 (37.0)
			95% CI[a]	(46.59, 60.55)	(29.98, 43.93)
			Relative Risk (95% CI)[a]	1.45 (1.15, 1.82)	
			P-value	0.0015	
		Weight(kg): >100	N	34	45
			n (%)	17 (50.0)	11 (24.4)
			95% CI[a]	(33.19, 66.81)	(11.89, 37.00)
			Relative Risk (95% CI)[a]	2.05 (1.11, 3.78)	
			P-value	0.0223	
			Test for interaction[b]	0.8239	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Gastrointestinal disorders	Overall	Weight(kg): <70	N	132	136
			n (%)	35 (26.5)	3 (2.2)
			95% CI[a]	(18.98, 34.05)	(0.00, 4.67)
			Relative Risk (95% CI)[a]	12.02 (3.79, 38.13)	
			P-value	<.0001	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	31 (15.8)	4 (2.2)
			95% CI[a]	(10.71, 20.92)	(0.07, 4.28)
			Relative Risk (95% CI)[a]	7.28 (2.62, 20.21)	
			P-value	0.0001	
		Weight(kg): >100	N	34	45
			n (%)	4 (11.8)	4 (8.9)
			95% CI[a]	(0.93, 22.59)	(0.57, 17.20)
			Relative Risk (95% CI)[a]	1.32 (0.36, 4.92)	
			P-value	0.6755	
			Test for interaction[b]	0.0173	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Nausea	Weight(kg): <70	N	132	136
			n (%)	35 (26.5)	1 (0.7)
			95% CI[a]	(18.98, 34.05)	(0.00, 2.17)
			Relative Risk (95% CI)[a]	36.06 (5.01, 259.43)	
			P-value	0.0004	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	31 (15.8)	3 (1.6)
			95% CI[a]	(10.71, 20.92)	(0.00, 3.46)
			Relative Risk (95% CI)[a]	9.70 (3.02, 31.19)	
			P-value	0.0001	
		Weight(kg): >100	N	34	45
			n (%)	4 (11.8)	4 (8.9)
			95% CI[a]	(0.93, 22.59)	(0.57, 17.20)
			Relative Risk (95% CI)[a]	1.32 (0.36, 4.92)	
			P-value	0.6755	
			Test for interaction[b]	0.0092	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Vomiting	Weight(kg): <70	N	132	136
			n (%)	8 (6.1)	2 (1.5)
			95% CI[a]	(1.99, 10.13)	(0.00, 3.49)
			Relative Risk (95% CI)[a]	4.12 (0.89, 19.05)	
			P-value	0.0698	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	3 (1.5)	1 (0.5)
			95% CI[a]	(0.00, 3.25)	(0.00, 1.61)
			Relative Risk (95% CI)[a]	2.82 (0.30, 26.83)	
			P-value	0.3680	
		Weight(kg): >100	N	34	45
			n (%)	0	3 (6.7)
			95% CI[a]	(0.00, 10.28)	(0.00, 13.95)
			Relative Risk (95% CI)[a]	0.22 (0.01, 4.20)	
			P-value	0.3124	
			Test for interaction[b]	0.1135	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
General disorders and administration site conditions	Overall	Weight(kg): <70	N	132	136
			n (%)	7 (5.3)	2 (1.5)
			95% CI[a]	(1.48, 9.13)	(0.00, 3.49)
			Relative Risk (95% CI)[a]	3.61 (0.76, 17.04)	
			P-value	0.1055	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	3 (1.5)	2 (1.1)
			95% CI[a]	(0.00, 3.25)	(0.00, 2.59)
			Relative Risk (95% CI)[a]	1.41 (0.24, 8.33)	
			P-value	0.7059	
		Weight(kg): >100	N	34	45
			n (%)	0	1 (2.2)
			95% CI[a]	(0.00, 10.28)	(0.00, 6.53)
			Relative Risk (95% CI)[a]	0.65 (0.02, 18.88)	
			P-value	0.8034	
			Test for interaction[b]	0.3314	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Fatigue	Weight(kg): <70	N	132	136
			n (%)	7 (5.3)	2 (1.5)
			95% CI[a]	(1.48, 9.13)	(0.00, 3.49)
			Relative Risk (95% CI)[a]	3.61 (0.76, 17.04)	
			P-value	0.1055	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	3 (1.5)	2 (1.1)
			95% CI[a]	(0.00, 3.25)	(0.00, 2.59)
			Relative Risk (95% CI)[a]	1.41 (0.24, 8.33)	
			P-value	0.7059	
		Weight(kg): >100	N	34	45
			n (%)	0	1 (2.2)
			95% CI[a]	(0.00, 10.28)	(0.00, 6.53)
			Relative Risk (95% CI)[a]	0.65 (0.02, 18.88)	
			P-value	0.8034	
			Test for interaction[b]	0.3314	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Infections and infestations	Overall	Weight(kg): <70	N	132	136
			n (%)	21 (15.9)	30 (22.1)
			95% CI[a]	(9.67, 22.15)	(15.09, 29.03)
			Relative Risk (95% CI)[a]	0.72 (0.44, 1.19)	
			P-value	0.2034	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	41 (20.9)	41 (22.3)
			95% CI[a]	(15.22, 26.61)	(16.27, 28.30)
			Relative Risk (95% CI)[a]	0.94 (0.64, 1.38)	
			P-value	0.7466	
		Weight(kg): >100	N	34	45
			n (%)	6 (17.6)	5 (11.1)
			95% CI[a]	(4.83, 30.46)	(1.93, 20.29)
			Relative Risk (95% CI)[a]	1.59 (0.53, 4.77)	
			P-value	0.4098	
			Test for interaction[b]	0.3888	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	COVID-19	Weight(kg): <70	N	132	136
			n (%)	3 (2.3)	4 (2.9)
			95% CI[a]	(0.00, 4.82)	(0.10, 5.78)
			Relative Risk (95% CI)[a]	0.77 (0.18, 3.39)	
			P-value	0.7324	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	10 (5.1)	7 (3.8)
			95% CI[a]	(2.02, 8.18)	(1.04, 6.57)
			Relative Risk (95% CI)[a]	1.34 (0.52, 3.45)	
			P-value	0.5426	
		Weight(kg): >100	N	34	45
			n (%)	2 (5.9)	1 (2.2)
			95% CI[a]	(0.00, 13.79)	(0.00, 6.53)
			Relative Risk (95% CI)[a]	2.65 (0.25, 28.00)	
			P-value	0.4186	
			Test for interaction[b]	0.6152	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Conjunctivitis	Weight(kg): <70	N	132	136
			n (%)	2 (1.5)	15 (11.0)
			95% CI[a]	(0.00, 3.60)	(5.76, 16.29)
			Relative Risk (95% CI)[a]	0.14 (0.03, 0.59)	
			P-value	0.0075	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	6 (3.1)	17 (9.2)
			95% CI[a]	(0.65, 5.47)	(5.06, 13.42)
			Relative Risk (95% CI)[a]	0.33 (0.13, 0.82)	
			P-value	0.0172	
		Weight(kg): >100	N	34	45
			n (%)	0	3 (6.7)
			95% CI[a]	(0.00, 10.28)	(0.00, 13.95)
			Relative Risk (95% CI)[a]	0.22 (0.01, 4.20)	
			P-value	0.3124	
			Test for interaction[b]	0.6025	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Folliculitis	Weight(kg): <70	N	132	136
			n (%)	2 (1.5)	2 (1.5)
			95% CI[a]	(0.00, 3.60)	(0.00, 3.49)
			Relative Risk (95% CI)[a]	1.03 (0.15, 7.21)	
			P-value	0.9760	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	9 (4.6)	1 (0.5)
			95% CI[a]	(1.66, 7.52)	(0.00, 1.61)
			Relative Risk (95% CI)[a]	8.45 (1.08, 66.04)	
			P-value	0.0419	
		Weight(kg): >100	N	34	45
			n (%)	1 (2.9)	0
			95% CI[a]	(0.00, 8.62)	(0.00, 7.87)
			Relative Risk (95% CI)[a]	2.68 (0.09, 77.48)	
			P-value	0.5664	
			Test for interaction[b]	0.1856	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Herpes simplex	Weight(kg): <70	N	132	136
			n (%)	4 (3.0)	3 (2.2)
			95% CI[a]	(0.11, 5.95)	(0.00, 4.67)
			Relative Risk (95% CI)[a]	1.37 (0.31, 6.02)	
			P-value	0.6736	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	8 (4.1)	2 (1.1)
			95% CI[a]	(1.31, 6.85)	(0.00, 2.59)
			Relative Risk (95% CI)[a]	3.76 (0.81, 17.45)	
			P-value	0.0914	
		Weight(kg): >100	N	34	45
			n (%)	0	0
			Test for interaction[b]	0.5701	
	Nasopharyngitis	Weight(kg): <70	N	132	136
			n (%)	5 (3.8)	5 (3.7)
			95% CI[a]	(0.53, 7.04)	(0.51, 6.84)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.03 (0.31, 3.48)	
			P-value	0.9616	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	9 (4.6)	6 (3.3)
			95% CI[a]	(1.66, 7.52)	(0.69, 5.83)
			Relative Risk (95% CI)[a]	1.41 (0.51, 3.88)	
			P-value	0.5079	
		Weight(kg): >100	N	34	45
			n (%)	0	1 (2.2)
			95% CI[a]	(0.00, 10.28)	(0.00, 6.53)
			Relative Risk (95% CI)[a]	0.65 (0.02, 18.88)	
			P-value	0.8034	
			Test for interaction[b]	0.8244	
	Oral herpes	Weight(kg): <70	N	132	136
			n (%)	5 (3.8)	6 (4.4)
			95% CI[a]	(0.53, 7.04)	(0.96, 7.86)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.86 (0.27, 2.75)	
			P-value	0.7971	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	3 (1.5)	8 (4.3)
			95% CI[a]	(0.00, 3.25)	(1.40, 7.29)
			Relative Risk (95% CI)[a]	0.35 (0.09, 1.31)	
			P-value	0.1187	
		Weight(kg): >100	N	34	45
			n (%)	1 (2.9)	1 (2.2)
			95% CI[a]	(0.00, 8.62)	(0.00, 6.53)
			Relative Risk (95% CI)[a]	1.32 (0.09, 20.41)	
			P-value	0.8408	
			Test for interaction[b]	0.5945	
	Upper respiratory tract infection	Weight(kg): <70	N	132	136
			n (%)	3 (2.3)	4 (2.9)
			95% CI[a]	(0.00, 4.82)	(0.10, 5.78)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.77 (0.18, 3.39)	
			P-value	0.7324	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	5 (2.6)	5 (2.7)
			95% CI[a]	(0.34, 4.76)	(0.37, 5.07)
			Relative Risk (95% CI)[a]	0.94 (0.28, 3.19)	
			P-value	0.9194	
		Weight(kg): >100	N	34	45
			n (%)	2 (5.9)	0
			95% CI[a]	(0.00, 13.79)	(0.00, 7.87)
			Relative Risk (95% CI)[a]	5.35 (0.25, 114.96)	
			P-value	0.2837	
			Test for interaction[b]	0.5199	
Investigations	Overall	Weight(kg): <70	N	132	136
			n (%)	13 (9.8)	8 (5.9)
			95% CI[a]	(4.77, 14.93)	(1.93, 9.84)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.67 (0.72, 3.91)	
			P-value	0.2333	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	22 (11.2)	17 (9.2)
			95% CI[a]	(6.81, 15.64)	(5.06, 13.42)
			Relative Risk (95% CI)[a]	1.21 (0.67, 2.21)	
			P-value	0.5249	
		Weight(kg): >100	N	34	45
			n (%)	3 (8.8)	1 (2.2)
			95% CI[a]	(0.00, 18.36)	(0.00, 6.53)
			Relative Risk (95% CI)[a]	3.97 (0.43, 36.52)	
			P-value	0.2232	
			Test for interaction[b]	0.7657	
	Blood creatine phosphokinase increased	Weight(kg): <70	N	132	136
			n (%)	3 (2.3)	4 (2.9)
			95% CI[a]	(0.00, 4.82)	(0.10, 5.78)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.77 (0.18, 3.39)	
			P-value	0.7324	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	9 (4.6)	9 (4.9)
			95% CI[a]	(1.66, 7.52)	(1.77, 8.01)
			Relative Risk (95% CI)[a]	0.94 (0.38, 2.31)	
			P-value	0.8908	
		Weight(kg): >100	N	34	45
			n (%)	2 (5.9)	0
			95% CI[a]	(0.00, 13.79)	(0.00, 7.87)
			Relative Risk (95% CI)[a]	5.35 (0.25, 114.96)	
			P-value	0.2837	
			Test for interaction[b]	0.5176	
	Natural killer cell count decreased	Weight(kg): <70	N	132	136
			n (%)	7 (5.3)	0
			95% CI[a]	(1.48, 9.13)	(0.00, 2.68)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	14.48 (0.83, 252.57)	
			P-value	0.0669	
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	3 (1.5)	0
			95% CI[a]	(0.00, 3.25)	(0.00, 1.98)
			Relative Risk (95% CI)[a]	5.65 (0.28, 111.99)	
			P-value	0.2560	
		Weight(kg): >100	N	34	45
			n (%)	0	0
			Test for interaction[b]	0.2238	
	SARS-CoV-2 test positive	Weight(kg): <70	N	132	136
			n (%)	3 (2.3)	4 (2.9)
			95% CI[a]	(0.00, 4.82)	(0.10, 5.78)
			Relative Risk (95% CI)[a]	0.77 (0.18, 3.39)	
			P-value	0.7324	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	11 (5.6)	8 (4.3)
			95% CI[a]	(2.39, 8.83)	(1.40, 7.29)
			Relative Risk (95% CI)[a]	1.29 (0.53, 3.14)	
			P-value	0.5732	
		Weight(kg): >100	N	34	45
			n (%)	1 (2.9)	1 (2.2)
			95% CI[a]	(0.00, 8.62)	(0.00, 6.53)
			Relative Risk (95% CI)[a]	1.32 (0.09, 20.41)	
			P-value	0.8408	
			Test for interaction[b]	0.7989	
Nervous system disorders	Overall	Weight(kg): <70	N	132	136
			n (%)	21 (15.9)	11 (8.1)
			95% CI[a]	(9.67, 22.15)	(3.51, 12.67)
			Relative Risk (95% CI)[a]	1.97 (0.99, 3.92)	
			P-value	0.0543	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	28 (14.3)	11 (6.0)
			95% CI[a]	(9.39, 19.18)	(2.55, 9.40)
			Relative Risk (95% CI)[a]	2.39 (1.23, 4.66)	
			P-value	0.0106	
		Weight(kg): >100	N	34	45
			n (%)	6 (17.6)	5 (11.1)
			95% CI[a]	(4.83, 30.46)	(1.93, 20.29)
			Relative Risk (95% CI)[a]	1.59 (0.53, 4.77)	
			P-value	0.4098	
			Test for interaction[b]	0.9870	
	Dizziness	Weight(kg): <70	N	132	136
			n (%)	5 (3.8)	2 (1.5)
			95% CI[a]	(0.53, 7.04)	(0.00, 3.49)
			Relative Risk (95% CI)[a]	2.58 (0.51, 13.04)	
			P-value	0.2530	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	4 (2.0)	1 (0.5)
			95% CI[a]	(0.06, 4.02)	(0.00, 1.61)
			Relative Risk (95% CI)[a]	3.76 (0.42, 33.29)	
			P-value	0.2347	
		Weight(kg): >100	N	34	45
			n (%)	1 (2.9)	1 (2.2)
			95% CI[a]	(0.00, 8.62)	(0.00, 6.53)
			Relative Risk (95% CI)[a]	1.32 (0.09, 20.41)	
			P-value	0.8408	
			Test for interaction[b]	0.9035	
	Headache	Weight(kg): <70	N	132	136
			n (%)	16 (12.1)	10 (7.4)
			95% CI[a]	(6.55, 17.69)	(2.97, 11.74)
			Relative Risk (95% CI)[a]	1.65 (0.78, 3.50)	
			P-value	0.1932	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	25 (12.8)	10 (5.4)
			95% CI[a]	(8.08, 17.43)	(2.16, 8.71)
			Relative Risk (95% CI)[a]	2.35 (1.16, 4.75)	
			P-value	0.0177	
		Weight(kg): >100	N	34	45
			n (%)	6 (17.6)	4 (8.9)
			95% CI[a]	(4.83, 30.46)	(0.57, 17.20)
			Relative Risk (95% CI)[a]	1.99 (0.61, 6.49)	
			P-value	0.2564	
			Test for interaction[b]	0.8210	
Skin and subcutaneous tissue disorders	Overall	Weight(kg): <70	N	132	136
			n (%)	26 (19.7)	6 (4.4)
			95% CI[a]	(12.91, 26.48)	(0.96, 7.86)
			Relative Risk (95% CI)[a]	4.46 (1.90, 10.50)	
			P-value	0.0006	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	32 (16.3)	15 (8.2)
			95% CI[a]	(11.15, 21.50)	(4.20, 12.11)
			Relative Risk (95% CI)[a]	2.00 (1.12, 3.57)	
			P-value	0.0188	
		Weight(kg): >100	N	34	45
			n (%)	3 (8.8)	2 (4.4)
			95% CI[a]	(0.00, 18.36)	(0.00, 10.47)
			Relative Risk (95% CI)[a]	1.99 (0.35, 11.23)	
			P-value	0.4380	
			Test for interaction[b]	0.2130	
	Acne	Weight(kg): <70	N	132	136
			n (%)	19 (14.4)	3 (2.2)
			95% CI[a]	(8.41, 20.38)	(0.00, 4.67)
			Relative Risk (95% CI)[a]	6.53 (1.98, 21.53)	
			P-value	0.0021	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	24 (12.2)	7 (3.8)
			95% CI[a]	(7.66, 16.83)	(1.04, 6.57)
			Relative Risk (95% CI)[a]	3.22 (1.42, 7.29)	
			P-value	0.0051	
		Weight(kg): >100	N	34	45
			n (%)	3 (8.8)	0
			95% CI[a]	(0.00, 18.36)	(0.00, 7.87)
			Relative Risk (95% CI)[a]	8.03 (0.42, 155.07)	
			P-value	0.1679	
			Test for interaction[b]	0.6330	
	Dermatitis atopic	Weight(kg): <70	N	132	136
			n (%)	8 (6.1)	4 (2.9)
			95% CI[a]	(1.99, 10.13)	(0.10, 5.78)
			Relative Risk (95% CI)[a]	2.06 (0.64, 6.68)	
			P-value	0.2282	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
		Weight(kg): >=70 and <=100	N	196	184
			n (%)	9 (4.6)	8 (4.3)
			95% CI[a]	(1.66, 7.52)	(1.40, 7.29)
			Relative Risk (95% CI)[a]	1.06 (0.42, 2.68)	
			P-value	0.9085	
		Weight(kg): >100	N	34	45
			n (%)	0	2 (4.4)
			95% CI[a]	(0.00, 10.28)	(0.00, 10.47)
			Relative Risk (95% CI)[a]	0.33 (0.02, 7.00)	
			P-value	0.4739	
			Test for interaction[b]	0.3776	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	AD Duration (years) group: <26	N	222	220
			n (%)	115 (51.8)	65 (29.5)
			95% CI[a]	(45.23, 58.37)	(23.52, 35.57)
			Relative Risk (95% CI)[a]	1.75 (1.38, 2.23)	
			P-value	<.0001	
		AD Duration (years) group: >=26	N	140	145
			n (%)	82 (58.6)	64 (44.1)
			95% CI[a]	(50.41, 66.73)	(36.06, 52.22)
			Relative Risk (95% CI)[a]	1.33 (1.05, 1.67)	
			P-value	0.0159	
			Test for interaction[b]	0.5887	
Gastrointestinal disorders	Overall	AD Duration (years) group: <26	N	222	220
			n (%)	39 (17.6)	8 (3.6)
			95% CI[a]	(12.56, 22.57)	(1.16, 6.11)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	4.83 (2.31, 10.10)	
			P-value	<.0001	
		AD Duration (years) group: >=26	N	140	145
			n (%)	31 (22.1)	3 (2.1)
			95% CI[a]	(15.27, 29.02)	(0.00, 4.39)
			Relative Risk (95% CI)[a]	10.70 (3.35, 34.21)	
			P-value	<.0001	
			Test for interaction[b]	0.2029	
	Nausea	AD Duration (years) group: <26	N	222	220
			n (%)	39 (17.6)	7 (3.2)
			95% CI[a]	(12.56, 22.57)	(0.86, 5.50)
			Relative Risk (95% CI)[a]	5.52 (2.52, 12.08)	
			P-value	<.0001	
		AD Duration (years) group: >=26	N	140	145
			n (%)	31 (22.1)	1 (0.7)
			95% CI[a]	(15.27, 29.02)	(0.00, 2.04)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	32.11 (4.44, 232.02)	
			P-value	0.0006	
			Test for interaction[b]	0.1439	
	Vomiting	AD Duration (years) group: <26	N	222	220
			n (%)	10 (4.5)	3 (1.4)
			95% CI[a]	(1.78, 7.23)	(0.00, 2.90)
			Relative Risk (95% CI)[a]	3.30 (0.92, 11.84)	
			P-value	0.0666	
		AD Duration (years) group: >=26	N	140	145
			n (%)	1 (0.7)	3 (2.1)
			95% CI[a]	(0.00, 2.11)	(0.00, 4.39)
			Relative Risk (95% CI)[a]	0.35 (0.04, 3.28)	
			P-value	0.3545	
			Test for interaction[b]	0.0339	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
General disorders and administration site conditions	Overall	AD Duration (years) group: <26	N	222	220
			n (%)	4 (1.8)	4 (1.8)
			95% CI[a]	(0.05, 3.55)	(0.05, 3.58)
			Relative Risk (95% CI)[a]	0.99 (0.25, 3.91)	
			P-value	0.9897	
		AD Duration (years) group: >=26	N	140	145
			n (%)	6 (4.3)	1 (0.7)
			95% CI[a]	(0.93, 7.64)	(0.00, 2.04)
			Relative Risk (95% CI)[a]	6.21 (0.76, 50.96)	
			P-value	0.0888	
			Test for interaction[b]	0.1091	
	Fatigue	AD Duration (years) group: <26	N	222	220
			n (%)	4 (1.8)	4 (1.8)
			95% CI[a]	(0.05, 3.55)	(0.05, 3.58)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.99 (0.25, 3.91)	
			P-value	0.9897	
		AD Duration (years) group: >=26	N	140	145
			n (%)	6 (4.3)	1 (0.7)
			95% CI[a]	(0.93, 7.64)	(0.00, 2.04)
			Relative Risk (95% CI)[a]	6.21 (0.76, 50.96)	
			P-value	0.0888	
			Test for interaction[b]	0.1091	
Infections and infestations	Overall	AD Duration (years) group: <26	N	222	220
			n (%)	37 (16.7)	32 (14.5)
			95% CI[a]	(11.76, 21.57)	(9.89, 19.20)
			Relative Risk (95% CI)[a]	1.15 (0.74, 1.77)	
			P-value	0.5395	
		AD Duration (years) group: >=26	N	140	145
			n (%)	31 (22.1)	44 (30.3)
			95% CI[a]	(15.27, 29.02)	(22.86, 37.83)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.73 (0.49, 1.08)	
			P-value	0.1194	
			Test for interaction[b]	0.0958	
	COVID-19	AD Duration (years) group: <26	N	222	220
			n (%)	9 (4.1)	6 (2.7)
			95% CI[a]	(1.46, 6.65)	(0.58, 4.88)
			Relative Risk (95% CI)[a]	1.49 (0.54, 4.11)	
			P-value	0.4444	
		AD Duration (years) group: >=26	N	140	145
			n (%)	6 (4.3)	6 (4.1)
			95% CI[a]	(0.93, 7.64)	(0.90, 7.38)
			Relative Risk (95% CI)[a]	1.04 (0.34, 3.13)	
			P-value	0.9505	
			Test for interaction[b]	0.6902	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Conjunctivitis	AD Duration (years) group: <26	N	222	220
			n (%)	3 (1.4)	12 (5.5)
			95% CI[a]	(0.00, 2.87)	(2.45, 8.46)
			Relative Risk (95% CI)[a]	0.25 (0.07, 0.87)	
			P-value	0.0289	
		AD Duration (years) group: >=26	N	140	145
			n (%)	5 (3.6)	23 (15.9)
			95% CI[a]	(0.50, 6.65)	(9.92, 21.81)
			Relative Risk (95% CI)[a]	0.23 (0.09, 0.58)	
			P-value	0.0019	
			Test for interaction[b]	0.0308	
	Folliculitis	AD Duration (years) group: <26	N	222	220
			n (%)	7 (3.2)	0
			95% CI[a]	(0.85, 5.45)	(0.00, 1.66)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	13.91 (0.79, 243.55)	
			P-value	0.0715	
		AD Duration (years) group: >=26	N	140	145
			n (%)	5 (3.6)	3 (2.1)
			95% CI[a]	(0.50, 6.65)	(0.00, 4.39)
			Relative Risk (95% CI)[a]	1.73 (0.42, 7.09)	
			P-value	0.4487	
			Test for interaction[b]	0.5480	
	Herpes simplex	AD Duration (years) group: <26	N	222	220
			n (%)	5 (2.3)	1 (0.5)
			95% CI[a]	(0.30, 4.20)	(0.00, 1.34)
			Relative Risk (95% CI)[a]	4.95 (0.58, 42.07)	
			P-value	0.1425	
		AD Duration (years) group: >=26	N	140	145
			n (%)	7 (5.0)	4 (2.8)
			95% CI[a]	(1.39, 8.61)	(0.09, 5.42)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.81 (0.54, 6.06)	
			P-value	0.3339	
			Test for interaction[b]	0.8469	
	Nasopharyngitis	AD Duration (years) group: <26	N	222	220
			n (%)	8 (3.6)	6 (2.7)
			95% CI[a]	(1.15, 6.06)	(0.58, 4.88)
			Relative Risk (95% CI)[a]	1.32 (0.47, 3.75)	
			P-value	0.6002	
		AD Duration (years) group: >=26	N	140	145
			n (%)	6 (4.3)	6 (4.1)
			95% CI[a]	(0.93, 7.64)	(0.90, 7.38)
			Relative Risk (95% CI)[a]	1.04 (0.34, 3.13)	
			P-value	0.9505	
			Test for interaction[b]	0.8038	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Oral herpes	AD Duration (years) group: <26	N	222	220
			n (%)	5 (2.3)	5 (2.3)
			95% CI[a]	(0.30, 4.20)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	0.99 (0.29, 3.38)	
			P-value	0.9885	
		AD Duration (years) group: >=26	N	140	145
			n (%)	4 (2.9)	10 (6.9)
			95% CI[a]	(0.10, 5.62)	(2.77, 11.02)
			Relative Risk (95% CI)[a]	0.41 (0.13, 1.29)	
			P-value	0.1284	
			Test for interaction[b]	0.1659	
	Upper respiratory tract infection	AD Duration (years) group: <26	N	222	220
			n (%)	6 (2.7)	4 (1.8)
			95% CI[a]	(0.57, 4.84)	(0.05, 3.58)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.49 (0.43, 5.20)	
			P-value	0.5347	
		AD Duration (years) group: >=26	N	140	145
			n (%)	4 (2.9)	5 (3.4)
			95% CI[a]	(0.10, 5.62)	(0.48, 6.42)
			Relative Risk (95% CI)[a]	0.83 (0.23, 3.02)	
			P-value	0.7758	
			Test for interaction[b]	0.5570	
Investigations	Overall	AD Duration (years) group: <26	N	222	220
			n (%)	23 (10.4)	13 (5.9)
			95% CI[a]	(6.35, 14.37)	(2.79, 9.02)
			Relative Risk (95% CI)[a]	1.75 (0.91, 3.37)	
			P-value	0.0924	
		AD Duration (years) group: >=26	N	140	145
			n (%)	15 (10.7)	13 (9.0)
			95% CI[a]	(5.59, 15.84)	(4.32, 13.62)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.20 (0.59, 2.42)	
			P-value	0.6205	
			Test for interaction[b]	0.5481	
	Blood creatine phosphokinase increased	AD Duration (years) group: <26	N	222	220
			n (%)	9 (4.1)	7 (3.2)
			95% CI[a]	(1.46, 6.65)	(0.86, 5.50)
			Relative Risk (95% CI)[a]	1.27 (0.48, 3.36)	
			P-value	0.6245	
		AD Duration (years) group: >=26	N	140	145
			n (%)	5 (3.6)	6 (4.1)
			95% CI[a]	(0.50, 6.65)	(0.90, 7.38)
			Relative Risk (95% CI)[a]	0.86 (0.27, 2.76)	
			P-value	0.8042	
			Test for interaction[b]	0.6188	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Natural killer cell count decreased	AD Duration (years) group: <26	N	222	220
			n (%)	4 (1.8)	0
			95% CI[a]	(0.05, 3.55)	(0.00, 1.66)
			Relative Risk (95% CI)[a]	7.95 (0.42, 149.41)	
			P-value	0.1662	
		AD Duration (years) group: >=26	N	140	145
			n (%)	6 (4.3)	0
			95% CI[a]	(0.93, 7.64)	(0.00, 2.51)
			Relative Risk (95% CI)[a]	12.47 (0.70, 221.20)	
			P-value	0.0854	
			Test for interaction[b]	0.2419	
	SARS-CoV-2 test positive	AD Duration (years) group: <26	N	222	220
			n (%)	10 (4.5)	6 (2.7)
			95% CI[a]	(1.78, 7.23)	(0.58, 4.88)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.65 (0.61, 4.47)	
			P-value	0.3229	
		AD Duration (years) group: >=26	N	140	145
			n (%)	5 (3.6)	7 (4.8)
			95% CI[a]	(0.50, 6.65)	(1.34, 8.32)
			Relative Risk (95% CI)[a]	0.74 (0.24, 2.28)	
			P-value	0.5992	
			Test for interaction[b]	0.3071	
Nervous system disorders	Overall	AD Duration (years) group: <26	N	222	220
			n (%)	34 (15.3)	14 (6.4)
			95% CI[a]	(10.58, 20.05)	(3.14, 9.59)
			Relative Risk (95% CI)[a]	2.41 (1.33, 4.36)	
			P-value	0.0037	
		AD Duration (years) group: >=26	N	140	145
			n (%)	21 (15.0)	13 (9.0)
			95% CI[a]	(9.09, 20.91)	(4.32, 13.62)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.67 (0.87, 3.21)	
			P-value	0.1216	
			Test for interaction[b]	0.5644	
	Dizziness	AD Duration (years) group: <26	N	222	220
			n (%)	8 (3.6)	1 (0.5)
			95% CI[a]	(1.15, 6.06)	(0.00, 1.34)
			Relative Risk (95% CI)[a]	7.93 (1.00, 62.86)	
			P-value	0.0500	
		AD Duration (years) group: >=26	N	140	145
			n (%)	2 (1.4)	3 (2.1)
			95% CI[a]	(0.00, 3.39)	(0.00, 4.39)
			Relative Risk (95% CI)[a]	0.69 (0.12, 4.07)	
			P-value	0.6824	
			Test for interaction[b]	0.0648	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Headache	AD Duration (years) group: <26	N	222	220
			n (%)	27 (12.2)	13 (5.9)
			95% CI[a]	(7.86, 16.46)	(2.79, 9.02)
			Relative Risk (95% CI)[a]	2.06 (1.09, 3.88)	
			P-value	0.0258	
		AD Duration (years) group: >=26	N	140	145
			n (%)	20 (14.3)	11 (7.6)
			95% CI[a]	(8.49, 20.08)	(3.28, 11.90)
			Relative Risk (95% CI)[a]	1.88 (0.94, 3.78)	
			P-value	0.0756	
			Test for interaction[b]	0.9000	
Skin and subcutaneous tissue disorders	Overall	AD Duration (years) group: <26	N	222	220
			n (%)	31 (14.0)	12 (5.5)
			95% CI[a]	(9.40, 18.52)	(2.45, 8.46)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.56 (1.35, 4.85)	
			P-value	0.0040	
		AD Duration (years) group: >=26	N	140	145
			n (%)	30 (21.4)	11 (7.6)
			95% CI[a]	(14.63, 28.23)	(3.28, 11.90)
			Relative Risk (95% CI)[a]	2.82 (1.47, 5.41)	
			P-value	0.0018	
			Test for interaction[b]	0.2512	
	Acne	AD Duration (years) group: <26	N	222	220
			n (%)	22 (9.9)	7 (3.2)
			95% CI[a]	(5.98, 13.84)	(0.86, 5.50)
			Relative Risk (95% CI)[a]	3.11 (1.36, 7.14)	
			P-value	0.0073	
		AD Duration (years) group: >=26	N	140	145
			n (%)	24 (17.1)	3 (2.1)
			95% CI[a]	(10.90, 23.39)	(0.00, 4.39)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	8.29 (2.55, 26.90)	
			P-value	0.0004	
			Test for interaction[b]	0.0458	
	Dermatitis atopic	AD Duration (years) group: <26	N	222	220
			n (%)	9 (4.1)	6 (2.7)
			95% CI[a]	(1.46, 6.65)	(0.58, 4.88)
			Relative Risk (95% CI)[a]	1.49 (0.54, 4.11)	
			P-value	0.4444	
		AD Duration (years) group: >=26	N	140	145
			n (%)	8 (5.7)	8 (5.5)
			95% CI[a]	(1.87, 9.56)	(1.80, 9.23)
			Relative Risk (95% CI)[a]	1.04 (0.40, 2.68)	
			P-value	0.9424	
			Test for interaction[b]	0.7317	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	Baseline EASI group: 16-25	N	181	183
			n (%)	99 (54.7)	69 (37.7)
			95% CI[a]	(47.44, 61.95)	(30.68, 44.73)
			Relative Risk (95% CI)[a]	1.45 (1.15, 1.82)	
			P-value	0.0014	
		Baseline EASI group: >25	N	172	174
			n (%)	93 (54.1)	58 (33.3)
			95% CI[a]	(46.62, 61.52)	(26.33, 40.34)
			Relative Risk (95% CI)[a]	1.62 (1.26, 2.09)	
			P-value	0.0002	
			Test for interaction[b]	0.6999	
		Baseline EASI group: Missing	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Gastrointestinal disorders	Overall	Baseline EASI group: 16-25	N	181	183
			n (%)	38 (21.0)	8 (4.4)
			95% CI[a]	(15.06, 26.93)	(1.41, 7.33)
			Relative Risk (95% CI)[a]	4.80 (2.30, 10.01)	
			P-value	<.0001	
		Baseline EASI group: >25	N	172	174
			n (%)	30 (17.4)	2 (1.1)
			95% CI[a]	(11.77, 23.11)	(0.00, 2.73)
			Relative Risk (95% CI)[a]	15.17 (3.68, 62.51)	
			P-value	0.0002	
			Test for interaction[b]	0.8434	
	Nausea	Baseline EASI group: 16-25	N	181	183
			n (%)	38 (21.0)	6 (3.3)
			95% CI[a]	(15.06, 26.93)	(0.70, 5.86)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	6.40 (2.78, 14.78)	
			P-value	<.0001	
		Baseline EASI group: >25	N	172	174
			n (%)	30 (17.4)	1 (0.6)
			95% CI[a]	(11.77, 23.11)	(0.00, 1.70)
			Relative Risk (95% CI)[a]	30.35 (4.19, 220.07)	
			P-value	0.0007	
			Test for interaction[b]	0.7611	
	Vomiting	Baseline EASI group: 16-25	N	181	183
			n (%)	6 (3.3)	4 (2.2)
			95% CI[a]	(0.71, 5.92)	(0.07, 4.30)
			Relative Risk (95% CI)[a]	1.52 (0.44, 5.28)	
			P-value	0.5132	
		Baseline EASI group: >25	N	172	174
			n (%)	5 (2.9)	2 (1.1)
			95% CI[a]	(0.40, 5.42)	(0.00, 2.73)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.53 (0.50, 12.86)	
			P-value	0.2635	
			Test for interaction[b]	0.7877	
General disorders and administration site conditions	Overall	Baseline EASI group: 16-25	N	181	183
			n (%)	4 (2.2)	3 (1.6)
			95% CI[a]	(0.07, 4.35)	(0.00, 3.48)
			Relative Risk (95% CI)[a]	1.35 (0.31, 5.94)	
			P-value	0.6930	
		Baseline EASI group: >25	N	172	174
			n (%)	6 (3.5)	2 (1.1)
			95% CI[a]	(0.75, 6.23)	(0.00, 2.73)
			Relative Risk (95% CI)[a]	3.03 (0.62, 14.83)	
			P-value	0.1702	
			Test for interaction[b]	0.4142	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Fatigue	Baseline EASI group: 16-25	N	181	183
			n (%)	4 (2.2)	3 (1.6)
			95% CI[a]	(0.07, 4.35)	(0.00, 3.48)
			Relative Risk (95% CI)[a]	1.35 (0.31, 5.94)	
			P-value	0.6930	
		Baseline EASI group: >25	N	172	174
			n (%)	6 (3.5)	2 (1.1)
			95% CI[a]	(0.75, 6.23)	(0.00, 2.73)
			Relative Risk (95% CI)[a]	3.03 (0.62, 14.83)	
			P-value	0.1702	
			Test for interaction[b]	0.4142	
Infections and infestations	Overall	Baseline EASI group: 16-25	N	181	183
			n (%)	35 (19.3)	38 (20.8)
			95% CI[a]	(13.58, 25.09)	(14.89, 26.64)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.93 (0.62, 1.40)	
			P-value	0.7338	
		Baseline EASI group: >25	N	172	174
			n (%)	31 (18.0)	38 (21.8)
			95% CI[a]	(12.28, 23.77)	(15.70, 27.98)
			Relative Risk (95% CI)[a]	0.83 (0.54, 1.26)	
			P-value	0.3758	
			Test for interaction[b]	0.6915	
	COVID-19	Baseline EASI group: 16-25	N	181	183
			n (%)	5 (2.8)	4 (2.2)
			95% CI[a]	(0.37, 5.15)	(0.07, 4.30)
			Relative Risk (95% CI)[a]	1.26 (0.34, 4.63)	
			P-value	0.7238	
		Baseline EASI group: >25	N	172	174
			n (%)	10 (5.8)	8 (4.6)
			95% CI[a]	(2.32, 9.31)	(1.49, 7.71)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.26 (0.51, 3.13)	
			P-value	0.6114	
			Test for interaction[b]	0.8191	
	Conjunctivitis	Baseline EASI group: 16-25	N	181	183
			n (%)	3 (1.7)	20 (10.9)
			95% CI[a]	(0.00, 3.52)	(6.41, 15.45)
			Relative Risk (95% CI)[a]	0.15 (0.05, 0.50)	
			P-value	0.0020	
		Baseline EASI group: >25	N	172	174
			n (%)	5 (2.9)	15 (8.6)
			95% CI[a]	(0.40, 5.42)	(4.45, 12.79)
			Relative Risk (95% CI)[a]	0.34 (0.13, 0.91)	
			P-value	0.0314	
			Test for interaction[b]	0.3185	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Folliculitis	Baseline EASI group: 16-25	N	181	183
			n (%)	8 (4.4)	1 (0.5)
			95% CI[a]	(1.43, 7.41)	(0.00, 1.61)
			Relative Risk (95% CI)[a]	8.09 (1.02, 64.01)	
			P-value	0.0476	
		Baseline EASI group: >25	N	172	174
			n (%)	4 (2.3)	2 (1.1)
			95% CI[a]	(0.07, 4.58)	(0.00, 2.73)
			Relative Risk (95% CI)[a]	2.02 (0.38, 10.90)	
			P-value	0.4122	
			Test for interaction[b]	0.2102	
	Herpes simplex	Baseline EASI group: 16-25	N	181	183
			n (%)	6 (3.3)	0
			95% CI[a]	(0.71, 5.92)	(0.00, 2.00)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	12.17 (0.68, 216.22)	
			P-value	0.0888	
		Baseline EASI group: >25	N	172	174
			n (%)	6 (3.5)	5 (2.9)
			95% CI[a]	(0.75, 6.23)	(0.39, 5.36)
			Relative Risk (95% CI)[a]	1.21 (0.38, 3.90)	
			P-value	0.7449	
			Test for interaction[b]	0.3083	
	Nasopharyngitis	Baseline EASI group: 16-25	N	181	183
			n (%)	7 (3.9)	7 (3.8)
			95% CI[a]	(1.06, 6.68)	(1.05, 6.60)
			Relative Risk (95% CI)[a]	1.01 (0.36, 2.82)	
			P-value	0.9833	
		Baseline EASI group: >25	N	172	174
			n (%)	6 (3.5)	5 (2.9)
			95% CI[a]	(0.75, 6.23)	(0.39, 5.36)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.21 (0.38, 3.90)	
			P-value	0.7449	
			Test for interaction[b]	0.8365	
	Oral herpes	Baseline EASI group: 16-25	N	181	183
			n (%)	5 (2.8)	6 (3.3)
			95% CI[a]	(0.37, 5.15)	(0.70, 5.86)
			Relative Risk (95% CI)[a]	0.84 (0.26, 2.71)	
			P-value	0.7739	
		Baseline EASI group: >25	N	172	174
			n (%)	3 (1.7)	9 (5.2)
			95% CI[a]	(0.00, 3.70)	(1.88, 8.46)
			Relative Risk (95% CI)[a]	0.34 (0.09, 1.22)	
			P-value	0.0985	
			Test for interaction[b]	0.2731	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Upper respiratory tract infection	Baseline EASI group: 16-25	N	181	183
			n (%)	6 (3.3)	3 (1.6)
			95% CI[a]	(0.71, 5.92)	(0.00, 3.48)
			Relative Risk (95% CI)[a]	2.02 (0.51, 7.96)	
			P-value	0.3140	
		Baseline EASI group: >25	N	172	174
			n (%)	3 (1.7)	6 (3.4)
			95% CI[a]	(0.00, 3.70)	(0.74, 6.16)
			Relative Risk (95% CI)[a]	0.51 (0.13, 1.99)	
			P-value	0.3294	
			Test for interaction[b]	0.1530	
Investigations	Overall	Baseline EASI group: 16-25	N	181	183
			n (%)	17 (9.4)	11 (6.0)
			95% CI[a]	(5.14, 13.64)	(2.57, 9.45)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.56 (0.75, 3.24)	
			P-value	0.2308	
		Baseline EASI group: >25	N	172	174
			n (%)	21 (12.2)	15 (8.6)
			95% CI[a]	(7.32, 17.10)	(4.45, 12.79)
			Relative Risk (95% CI)[a]	1.42 (0.76, 2.65)	
			P-value	0.2775	
			Test for interaction[b]	0.9427	
	Blood creatine phosphokinase increased	Baseline EASI group: 16-25	N	181	183
			n (%)	6 (3.3)	7 (3.8)
			95% CI[a]	(0.71, 5.92)	(1.05, 6.60)
			Relative Risk (95% CI)[a]	0.87 (0.30, 2.53)	
			P-value	0.7933	
		Baseline EASI group: >25	N	172	174
			n (%)	8 (4.7)	6 (3.4)
			95% CI[a]	(1.50, 7.80)	(0.74, 6.16)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.35 (0.48, 3.81)	
			P-value	0.5718	
			Test for interaction[b]	0.5514	
	Natural killer cell count decreased	Baseline EASI group: 16-25	N	181	183
			n (%)	5 (2.8)	0
			95% CI[a]	(0.37, 5.15)	(0.00, 2.00)
			Relative Risk (95% CI)[a]	10.14 (0.56, 184.22)	
			P-value	0.1175	
		Baseline EASI group: >25	N	172	174
			n (%)	5 (2.9)	0
			95% CI[a]	(0.40, 5.42)	(0.00, 2.10)
			Relative Risk (95% CI)[a]	10.15 (0.56, 184.28)	
			P-value	0.1173	
			Test for interaction[b]	0.9436	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	SARS-CoV-2 test positive	Baseline EASI group: 16-25	N	181	183
			n (%)	6 (3.3)	4 (2.2)
			95% CI[a]	(0.71, 5.92)	(0.07, 4.30)
			Relative Risk (95% CI)[a]	1.52 (0.44, 5.28)	
			P-value	0.5132	
		Baseline EASI group: >25	N	172	174
			n (%)	9 (5.2)	9 (5.2)
			95% CI[a]	(1.90, 8.56)	(1.88, 8.46)
			Relative Risk (95% CI)[a]	1.01 (0.41, 2.49)	
			P-value	0.9799	
			Test for interaction[b]	0.7212	
Nervous system disorders	Overall	Baseline EASI group: 16-25	N	181	183
			n (%)	21 (11.6)	19 (10.4)
			95% CI[a]	(6.94, 16.27)	(5.96, 14.80)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.12 (0.62, 2.01)	
			P-value	0.7101	
		Baseline EASI group: >25	N	172	174
			n (%)	33 (19.2)	8 (4.6)
			95% CI[a]	(13.30, 25.07)	(1.49, 7.71)
			Relative Risk (95% CI)[a]	4.17 (1.98, 8.77)	
			P-value	0.0002	
			Test for interaction[b]	0.0056	
	Dizziness	Baseline EASI group: 16-25	N	181	183
			n (%)	3 (1.7)	2 (1.1)
			95% CI[a]	(0.00, 3.52)	(0.00, 2.60)
			Relative Risk (95% CI)[a]	1.52 (0.26, 8.97)	
			P-value	0.6461	
		Baseline EASI group: >25	N	172	174
			n (%)	7 (4.1)	2 (1.1)
			95% CI[a]	(1.12, 7.02)	(0.00, 2.73)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	3.54 (0.75, 16.80)	
			P-value	0.1116	
			Test for interaction[b]	0.2615	
	Headache	Baseline EASI group: 16-25	N	181	183
			n (%)	18 (9.9)	17 (9.3)
			95% CI[a]	(5.59, 14.30)	(5.08, 13.50)
			Relative Risk (95% CI)[a]	1.07 (0.57, 2.01)	
			P-value	0.8322	
		Baseline EASI group: >25	N	172	174
			n (%)	28 (16.3)	7 (4.0)
			95% CI[a]	(10.76, 21.80)	(1.10, 6.94)
			Relative Risk (95% CI)[a]	4.05 (1.82, 9.01)	
			P-value	0.0006	
			Test for interaction[b]	0.0103	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Skin and subcutaneous tissue disorders	Overall	Baseline EASI group: 16-25	N	181	183
			n (%)	31 (17.1)	12 (6.6)
			95% CI[a]	(11.64, 22.62)	(2.97, 10.14)
			Relative Risk (95% CI)[a]	2.61 (1.39, 4.92)	
			P-value	0.0030	
		Baseline EASI group: >25	N	172	174
			n (%)	28 (16.3)	10 (5.7)
			95% CI[a]	(10.76, 21.80)	(2.29, 9.21)
			Relative Risk (95% CI)[a]	2.83 (1.42, 5.65)	
			P-value	0.0031	
			Test for interaction[b]	0.9775	
	Acne	Baseline EASI group: 16-25	N	181	183
			n (%)	25 (13.8)	6 (3.3)
			95% CI[a]	(8.79, 18.84)	(0.70, 5.86)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	4.21 (1.77, 10.03)	
			P-value	0.0011	
		Baseline EASI group: >25	N	172	174
			n (%)	19 (11.0)	4 (2.3)
			95% CI[a]	(6.36, 15.73)	(0.07, 4.53)
			Relative Risk (95% CI)[a]	4.81 (1.67, 13.83)	
			P-value	0.0036	
			Test for interaction[b]	0.6243	
	Dermatitis atopic	Baseline EASI group: 16-25	N	181	183
			n (%)	8 (4.4)	7 (3.8)
			95% CI[a]	(1.43, 7.41)	(1.05, 6.60)
			Relative Risk (95% CI)[a]	1.16 (0.43, 3.12)	
			P-value	0.7755	
		Baseline EASI group: >25	N	172	174
			n (%)	9 (5.2)	6 (3.4)
			95% CI[a]	(1.90, 8.56)	(0.74, 6.16)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.52 (0.55, 4.17)	
			P-value	0.4189	
			Test for interaction[b]	0.6937	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	Baseline %BSA group: 10-30	N	122	133
			n (%)	59 (48.4)	40 (30.1)
			95% CI[a]	(39.49, 57.23)	(22.28, 37.87)
			Relative Risk (95% CI)[a]	1.61 (1.17, 2.21)	
			P-value	0.0034	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	73 (55.3)	46 (38.0)
			95% CI[a]	(46.82, 63.78)	(29.37, 46.67)
			Relative Risk (95% CI)[a]	1.45 (1.11, 1.91)	
			P-value	0.0074	
		Baseline %BSA group: >50	N	108	111
			n (%)	65 (60.2)	43 (38.7)
			95% CI[a]	(50.95, 69.42)	(29.68, 47.80)
			Relative Risk (95% CI)[a]	1.55 (1.17, 2.06)	
			P-value	0.0020	
			Test for interaction[b]	0.7575	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Gastrointestinal disorders	Overall	Baseline %BSA group: 10-30	N	122	133
			n (%)	20 (16.4)	5 (3.8)
			95% CI[a]	(9.82, 22.96)	(0.53, 6.99)
			Relative Risk (95% CI)[a]	4.36 (1.69, 11.26)	
			P-value	0.0023	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	29 (22.0)	5 (4.1)
			95% CI[a]	(14.91, 29.03)	(0.59, 7.68)
			Relative Risk (95% CI)[a]	5.32 (2.13, 13.29)	
			P-value	0.0004	
		Baseline %BSA group: >50	N	108	111
			n (%)	21 (19.4)	1 (0.9)
			95% CI[a]	(11.98, 26.91)	(0.00, 2.66)
			Relative Risk (95% CI)[a]	21.58 (2.95, 157.66)	
			P-value	0.0025	
			Test for interaction[b]	0.4972	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Nausea	Baseline %BSA group: 10-30	N	122	133
			n (%)	20 (16.4)	5 (3.8)
			95% CI[a]	(9.82, 22.96)	(0.53, 6.99)
			Relative Risk (95% CI)[a]	4.36 (1.69, 11.26)	
			P-value	0.0023	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	29 (22.0)	2 (1.7)
			95% CI[a]	(14.91, 29.03)	(0.00, 3.92)
			Relative Risk (95% CI)[a]	13.29 (3.24, 54.52)	
			P-value	0.0003	
		Baseline %BSA group: >50	N	108	111
			n (%)	21 (19.4)	1 (0.9)
			95% CI[a]	(11.98, 26.91)	(0.00, 2.66)
			Relative Risk (95% CI)[a]	21.58 (2.95, 157.66)	
			P-value	0.0025	
			Test for interaction[b]	0.3398	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Vomiting	Baseline %BSA group: 10-30	N	122	133
			n (%)	4 (3.3)	2 (1.5)
			95% CI[a]	(0.12, 6.44)	(0.00, 3.57)
			Relative Risk (95% CI)[a]	2.18 (0.41, 11.69)	
			P-value	0.3630	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	5 (3.8)	3 (2.5)
			95% CI[a]	(0.53, 7.04)	(0.00, 5.25)
			Relative Risk (95% CI)[a]	1.53 (0.37, 6.26)	
			P-value	0.5558	
		Baseline %BSA group: >50	N	108	111
			n (%)	2 (1.9)	1 (0.9)
			95% CI[a]	(0.00, 4.39)	(0.00, 2.66)
			Relative Risk (95% CI)[a]	2.06 (0.19, 22.34)	
			P-value	0.5539	
			Test for interaction[b]	0.9452	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
General disorders and administration site conditions	Overall	Baseline %BSA group: 10-30	N	122	133
			n (%)	2 (1.6)	1 (0.8)
			95% CI[a]	(0.00, 3.89)	(0.00, 2.22)
			Relative Risk (95% CI)[a]	2.18 (0.20, 23.74)	
			P-value	0.5223	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	2 (1.5)	4 (3.3)
			95% CI[a]	(0.00, 3.60)	(0.12, 6.49)
			Relative Risk (95% CI)[a]	0.46 (0.09, 2.46)	
			P-value	0.3626	
		Baseline %BSA group: >50	N	108	111
			n (%)	6 (5.6)	0
			95% CI[a]	(1.24, 9.88)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	12.39 (0.70, 219.12)	
			P-value	0.0860	
			Test for interaction[b]	0.0770	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Fatigue	Baseline %BSA group: 10-30	N	122	133
			n (%)	2 (1.6)	1 (0.8)
			95% CI[a]	(0.00, 3.89)	(0.00, 2.22)
			Relative Risk (95% CI)[a]	2.18 (0.20, 23.74)	
			P-value	0.5223	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	2 (1.5)	4 (3.3)
			95% CI[a]	(0.00, 3.60)	(0.12, 6.49)
			Relative Risk (95% CI)[a]	0.46 (0.09, 2.46)	
			P-value	0.3626	
		Baseline %BSA group: >50	N	108	111
			n (%)	6 (5.6)	0
			95% CI[a]	(1.24, 9.88)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	12.39 (0.70, 219.12)	
			P-value	0.0860	
			Test for interaction[b]	0.0770	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Infections and infestations	Overall	Baseline %BSA group: 10-30	N	122	133
			n (%)	20 (16.4)	18 (13.5)
			95% CI[a]	(9.82, 22.96)	(7.72, 19.35)
			Relative Risk (95% CI)[a]	1.21 (0.67, 2.18)	
			P-value	0.5225	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	28 (21.2)	29 (24.0)
			95% CI[a]	(14.24, 28.19)	(16.36, 31.57)
			Relative Risk (95% CI)[a]	0.89 (0.56, 1.40)	
			P-value	0.6005	
		Baseline %BSA group: >50	N	108	111
			n (%)	20 (18.5)	29 (26.1)
			95% CI[a]	(11.19, 25.84)	(17.95, 34.30)
			Relative Risk (95% CI)[a]	0.71 (0.43, 1.17)	
			P-value	0.1811	
			Test for interaction[b]	0.3272	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	COVID-19	Baseline %BSA group: 10-30	N	122	133
			n (%)	4 (3.3)	2 (1.5)
			95% CI[a]	(0.12, 6.44)	(0.00, 3.57)
			Relative Risk (95% CI)[a]	2.18 (0.41, 11.69)	
			P-value	0.3630	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	5 (3.8)	4 (3.3)
			95% CI[a]	(0.53, 7.04)	(0.12, 6.49)
			Relative Risk (95% CI)[a]	1.15 (0.31, 4.17)	
			P-value	0.8363	
		Baseline %BSA group: >50	N	108	111
			n (%)	6 (5.6)	6 (5.4)
			95% CI[a]	(1.24, 9.88)	(1.20, 9.61)
			Relative Risk (95% CI)[a]	1.03 (0.34, 3.09)	
			P-value	0.9611	
			Test for interaction[b]	0.8707	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Conjunctivitis	Baseline %BSA group: 10-30	N	122	133
			n (%)	2 (1.6)	8 (6.0)
			95% CI[a]	(0.00, 3.89)	(1.97, 10.06)
			Relative Risk (95% CI)[a]	0.27 (0.06, 1.26)	
			P-value	0.0958	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	4 (3.0)	16 (13.2)
			95% CI[a]	(0.11, 5.95)	(7.19, 19.26)
			Relative Risk (95% CI)[a]	0.23 (0.08, 0.67)	
			P-value	0.0068	
		Baseline %BSA group: >50	N	108	111
			n (%)	2 (1.9)	11 (9.9)
			95% CI[a]	(0.00, 4.39)	(4.35, 15.47)
			Relative Risk (95% CI)[a]	0.19 (0.04, 0.82)	
			P-value	0.0267	
			Test for interaction[b]	0.3154	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Folliculitis	Baseline %BSA group: 10-30	N	122	133
			n (%)	5 (4.1)	1 (0.8)
			95% CI[a]	(0.58, 7.62)	(0.00, 2.22)
			Relative Risk (95% CI)[a]	5.45 (0.65, 46.00)	
			P-value	0.1192	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	5 (3.8)	2 (1.7)
			95% CI[a]	(0.53, 7.04)	(0.00, 3.92)
			Relative Risk (95% CI)[a]	2.29 (0.45, 11.59)	
			P-value	0.3161	
		Baseline %BSA group: >50	N	108	111
			n (%)	2 (1.9)	0
			95% CI[a]	(0.00, 4.39)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	4.13 (0.19, 90.54)	
			P-value	0.3680	
			Test for interaction[b]	0.7224	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Herpes simplex	Baseline %BSA group: 10-30	N	122	133
			n (%)	5 (4.1)	0
			95% CI[a]	(0.58, 7.62)	(0.00, 2.74)
			Relative Risk (95% CI)[a]	10.94 (0.60, 198.22)	
			P-value	0.1055	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	3 (2.3)	2 (1.7)
			95% CI[a]	(0.00, 4.82)	(0.00, 3.92)
			Relative Risk (95% CI)[a]	1.38 (0.23, 8.09)	
			P-value	0.7247	
		Baseline %BSA group: >50	N	108	111
			n (%)	4 (3.7)	3 (2.7)
			95% CI[a]	(0.14, 7.27)	(0.00, 5.72)
			Relative Risk (95% CI)[a]	1.37 (0.31, 5.98)	
			P-value	0.6751	
			Test for interaction[b]	0.4505	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Nasopharyngitis	Baseline %BSA group: 10-30	N	122	133
			n (%)	4 (3.3)	4 (3.0)
			95% CI[a]	(0.12, 6.44)	(0.10, 5.91)
			Relative Risk (95% CI)[a]	1.09 (0.28, 4.26)	
			P-value	0.9013	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	8 (6.1)	4 (3.3)
			95% CI[a]	(1.99, 10.13)	(0.12, 6.49)
			Relative Risk (95% CI)[a]	1.83 (0.57, 5.93)	
			P-value	0.3118	
		Baseline %BSA group: >50	N	108	111
			n (%)	2 (1.9)	4 (3.6)
			95% CI[a]	(0.00, 4.39)	(0.14, 7.07)
			Relative Risk (95% CI)[a]	0.51 (0.10, 2.75)	
			P-value	0.4364	
			Test for interaction[b]	0.4229	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Oral herpes	Baseline %BSA group: 10-30	N	122	133
			n (%)	3 (2.5)	4 (3.0)
			95% CI[a]	(0.00, 5.21)	(0.10, 5.91)
			Relative Risk (95% CI)[a]	0.82 (0.19, 3.58)	
			P-value	0.7893	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	2 (1.5)	6 (5.0)
			95% CI[a]	(0.00, 3.60)	(1.09, 8.83)
			Relative Risk (95% CI)[a]	0.31 (0.06, 1.49)	
			P-value	0.1417	
		Baseline %BSA group: >50	N	108	111
			n (%)	4 (3.7)	5 (4.5)
			95% CI[a]	(0.14, 7.27)	(0.65, 8.36)
			Relative Risk (95% CI)[a]	0.82 (0.23, 2.98)	
			P-value	0.7658	
			Test for interaction[b]	0.6009	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Upper respiratory tract infection	Baseline %BSA group: 10-30	N	122	133
			n (%)	2 (1.6)	2 (1.5)
			95% CI[a]	(0.00, 3.89)	(0.00, 3.57)
			Relative Risk (95% CI)[a]	1.09 (0.16, 7.62)	
			P-value	0.9307	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	5 (3.8)	2 (1.7)
			95% CI[a]	(0.53, 7.04)	(0.00, 3.92)
			Relative Risk (95% CI)[a]	2.29 (0.45, 11.59)	
			P-value	0.3161	
		Baseline %BSA group: >50	N	108	111
			n (%)	3 (2.8)	5 (4.5)
			95% CI[a]	(0.00, 5.88)	(0.65, 8.36)
			Relative Risk (95% CI)[a]	0.62 (0.15, 2.52)	
			P-value	0.5006	
			Test for interaction[b]	0.4817	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Investigations	Overall	Baseline %BSA group: 10-30	N	122	133
			n (%)	13 (10.7)	7 (5.3)
			95% CI[a]	(5.18, 16.13)	(1.47, 9.06)
			Relative Risk (95% CI)[a]	2.02 (0.84, 4.91)	
			P-value	0.1184	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	8 (6.1)	7 (5.8)
			95% CI[a]	(1.99, 10.13)	(1.63, 9.94)
			Relative Risk (95% CI)[a]	1.05 (0.39, 2.80)	
			P-value	0.9262	
		Baseline %BSA group: >50	N	108	111
			n (%)	17 (15.7)	12 (10.8)
			95% CI[a]	(8.87, 22.61)	(5.03, 16.59)
			Relative Risk (95% CI)[a]	1.46 (0.73, 2.90)	
			P-value	0.2858	
			Test for interaction[b]	0.4552	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Blood creatine phosphokinase increased	Baseline %BSA group: 10-30	N	122	133
			n (%)	5 (4.1)	4 (3.0)
			95% CI[a]	(0.58, 7.62)	(0.10, 5.91)
			Relative Risk (95% CI)[a]	1.36 (0.37, 4.96)	
			P-value	0.6386	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	1 (0.8)	4 (3.3)
			95% CI[a]	(0.00, 2.24)	(0.12, 6.49)
			Relative Risk (95% CI)[a]	0.23 (0.03, 2.02)	
			P-value	0.1848	
		Baseline %BSA group: >50	N	108	111
			n (%)	8 (7.4)	5 (4.5)
			95% CI[a]	(2.47, 12.35)	(0.65, 8.36)
			Relative Risk (95% CI)[a]	1.64 (0.56, 4.87)	
			P-value	0.3691	
			Test for interaction[b]	0.2399	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Natural killer cell count decreased	Baseline %BSA group: 10-30	N	122	133
			n (%)	2 (1.6)	0
			95% CI[a]	(0.00, 3.89)	(0.00, 2.74)
			Relative Risk (95% CI)[a]	4.38 (0.20, 96.12)	
			P-value	0.3489	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	4 (3.0)	0
			95% CI[a]	(0.11, 5.95)	(0.00, 3.00)
			Relative Risk (95% CI)[a]	7.36 (0.39, 137.85)	
			P-value	0.1816	
		Baseline %BSA group: >50	N	108	111
			n (%)	4 (3.7)	0
			95% CI[a]	(0.14, 7.27)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	8.26 (0.44, 154.37)	
			P-value	0.1576	
			Test for interaction[b]	0.6357	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	SARS-CoV-2 test positive	Baseline %BSA group: 10-30	N	122	133
			n (%)	6 (4.9)	3 (2.3)
			95% CI[a]	(1.08, 8.76)	(0.00, 4.78)
			Relative Risk (95% CI)[a]	2.18 (0.56, 8.53)	
			P-value	0.2627	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	3 (2.3)	3 (2.5)
			95% CI[a]	(0.00, 4.82)	(0.00, 5.25)
			Relative Risk (95% CI)[a]	0.92 (0.19, 4.46)	
			P-value	0.9141	
		Baseline %BSA group: >50	N	108	111
			n (%)	6 (5.6)	7 (6.3)
			95% CI[a]	(1.24, 9.88)	(1.78, 10.83)
			Relative Risk (95% CI)[a]	0.88 (0.31, 2.54)	
			P-value	0.8143	
			Test for interaction[b]	0.5710	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Nervous system disorders	Overall	Baseline %BSA group: 10-30	N	122	133
			n (%)	13 (10.7)	13 (9.8)
			95% CI[a]	(5.18, 16.13)	(4.73, 14.82)
			Relative Risk (95% CI)[a]	1.09 (0.53, 2.26)	
			P-value	0.8163	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	22 (16.7)	10 (8.3)
			95% CI[a]	(10.31, 23.02)	(3.36, 13.17)
			Relative Risk (95% CI)[a]	2.02 (1.00, 4.08)	
			P-value	0.0514	
		Baseline %BSA group: >50	N	108	111
			n (%)	20 (18.5)	4 (3.6)
			95% CI[a]	(11.19, 25.84)	(0.14, 7.07)
			Relative Risk (95% CI)[a]	5.14 (1.82, 14.54)	
			P-value	0.0020	
			Test for interaction[b]	0.0490	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Dizziness	Baseline %BSA group: 10-30	N	122	133
			n (%)	2 (1.6)	1 (0.8)
			95% CI[a]	(0.00, 3.89)	(0.00, 2.22)
			Relative Risk (95% CI)[a]	2.18 (0.20, 23.74)	
			P-value	0.5223	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	5 (3.8)	3 (2.5)
			95% CI[a]	(0.53, 7.04)	(0.00, 5.25)
			Relative Risk (95% CI)[a]	1.53 (0.37, 6.26)	
			P-value	0.5558	
		Baseline %BSA group: >50	N	108	111
			n (%)	3 (2.8)	0
			95% CI[a]	(0.00, 5.88)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	6.19 (0.31, 122.22)	
			P-value	0.2307	
			Test for interaction[b]	0.8044	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Headache	Baseline %BSA group: 10-30	N	122	133
			n (%)	11 (9.0)	12 (9.0)
			95% CI[a]	(3.93, 14.10)	(4.15, 13.89)
			Relative Risk (95% CI)[a]	1.00 (0.46, 2.18)	
			P-value	0.9986	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	18 (13.6)	8 (6.6)
			95% CI[a]	(7.78, 19.49)	(2.18, 11.04)
			Relative Risk (95% CI)[a]	2.06 (0.93, 4.57)	
			P-value	0.0745	
		Baseline %BSA group: >50	N	108	111
			n (%)	18 (16.7)	4 (3.6)
			95% CI[a]	(9.64, 23.70)	(0.14, 7.07)
			Relative Risk (95% CI)[a]	4.63 (1.62, 13.22)	
			P-value	0.0043	
			Test for interaction[b]	0.0555	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Skin and subcutaneous tissue disorders	Overall	Baseline %BSA group: 10-30	N	122	133
			n (%)	15 (12.3)	7 (5.3)
			95% CI[a]	(6.47, 18.12)	(1.47, 9.06)
			Relative Risk (95% CI)[a]	2.34 (0.99, 5.54)	
			P-value	0.0539	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	24 (18.2)	8 (6.6)
			95% CI[a]	(11.60, 24.76)	(2.18, 11.04)
			Relative Risk (95% CI)[a]	2.75 (1.28, 5.89)	
			P-value	0.0092	
		Baseline %BSA group: >50	N	108	111
			n (%)	22 (20.4)	8 (7.2)
			95% CI[a]	(12.77, 27.97)	(2.40, 12.02)
			Relative Risk (95% CI)[a]	2.83 (1.32, 6.07)	
			P-value	0.0077	
			Test for interaction[b]	0.4712	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Acne	Baseline %BSA group: 10-30	N	122	133
			n (%)	12 (9.8)	2 (1.5)
			95% CI[a]	(4.55, 15.12)	(0.00, 3.57)
			Relative Risk (95% CI)[a]	6.54 (1.49, 28.64)	
			P-value	0.0127	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	17 (12.9)	5 (4.1)
			95% CI[a]	(7.16, 18.59)	(0.59, 7.68)
			Relative Risk (95% CI)[a]	3.12 (1.19, 8.19)	
			P-value	0.0211	
		Baseline %BSA group: >50	N	108	111
			n (%)	17 (15.7)	3 (2.7)
			95% CI[a]	(8.87, 22.61)	(0.00, 5.72)
			Relative Risk (95% CI)[a]	5.82 (1.76, 19.31)	
			P-value	0.0040	
			Test for interaction[b]	0.5795	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Dermatitis atopic	Baseline %BSA group: 10-30	N	122	133
			n (%)	4 (3.3)	5 (3.8)
			95% CI[a]	(0.12, 6.44)	(0.53, 6.99)
			Relative Risk (95% CI)[a]	0.87 (0.24, 3.17)	
			P-value	0.8355	
		Baseline %BSA group: >30-50	N	132	121
			n (%)	8 (6.1)	4 (3.3)
			95% CI[a]	(1.99, 10.13)	(0.12, 6.49)
			Relative Risk (95% CI)[a]	1.83 (0.57, 5.93)	
			P-value	0.3118	
		Baseline %BSA group: >50	N	108	111
			n (%)	5 (4.6)	5 (4.5)
			95% CI[a]	(0.67, 8.59)	(0.65, 8.36)
			Relative Risk (95% CI)[a]	1.03 (0.31, 3.45)	
			P-value	0.9646	
			Test for interaction[b]	0.6344	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	Prior AD medications: Systemic Agents	N	172	176
			n (%)	95 (55.2)	62 (35.2)
			95% CI[a]	(47.80, 62.66)	(28.17, 42.28)
			Relative Risk (95% CI)[a]	1.57 (1.23, 2.00)	
			P-value	0.0003	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	101 (53.7)	67 (35.4)
			95% CI[a]	(46.60, 60.85)	(28.63, 42.27)
			Relative Risk (95% CI)[a]	1.52 (1.20, 1.91)	
			P-value	0.0005	
			Test for interaction[b]	0.7925	
		Prior AD medications: Missing	N	2	0
Gastrointestinal disorders	Overall	Prior AD medications: Systemic Agents	N	172	176
			n (%)	28 (16.3)	8 (4.5)
			95% CI[a]	(10.76, 21.80)	(1.47, 7.62)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	3.58 (1.68, 7.64)	
			P-value	0.0010	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	42 (22.3)	3 (1.6)
			95% CI[a]	(16.39, 28.29)	(0.00, 3.37)
			Relative Risk (95% CI)[a]	14.07 (4.44, 44.62)	
			P-value	<.0001	
			Test for interaction[b]	0.0544	
	Nausea	Prior AD medications: Systemic Agents	N	172	176
			n (%)	28 (16.3)	6 (3.4)
			95% CI[a]	(10.76, 21.80)	(0.73, 6.09)
			Relative Risk (95% CI)[a]	4.78 (2.03, 11.24)	
			P-value	0.0003	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	42 (22.3)	2 (1.1)
			95% CI[a]	(16.39, 28.29)	(0.00, 2.52)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	21.11 (5.18, 85.96)	
			P-value	<.0001	
			Test for interaction[b]	0.0663	
	Vomiting	Prior AD medications: Systemic Agents	N	172	176
			n (%)	4 (2.3)	4 (2.3)
			95% CI[a]	(0.07, 4.58)	(0.07, 4.47)
			Relative Risk (95% CI)[a]	1.02 (0.26, 4.03)	
			P-value	0.9738	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	7 (3.7)	2 (1.1)
			95% CI[a]	(1.02, 6.43)	(0.00, 2.52)
			Relative Risk (95% CI)[a]	3.52 (0.74, 16.72)	
			P-value	0.1136	
			Test for interaction[b]	0.2463	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
General disorders and administration site conditions	Overall	Prior AD medications: Systemic Agents	N	172	176
			n (%)	5 (2.9)	2 (1.1)
			95% CI[a]	(0.40, 5.42)	(0.00, 2.70)
			Relative Risk (95% CI)[a]	2.56 (0.50, 13.01)	
			P-value	0.2576	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	5 (2.7)	3 (1.6)
			95% CI[a]	(0.36, 4.96)	(0.00, 3.37)
			Relative Risk (95% CI)[a]	1.68 (0.41, 6.91)	
			P-value	0.4753	
			Test for interaction[b]	0.7427	
	Fatigue	Prior AD medications: Systemic Agents	N	172	176
			n (%)	5 (2.9)	2 (1.1)
			95% CI[a]	(0.40, 5.42)	(0.00, 2.70)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.56 (0.50, 13.01)	
			P-value	0.2576	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	5 (2.7)	3 (1.6)
			95% CI[a]	(0.36, 4.96)	(0.00, 3.37)
			Relative Risk (95% CI)[a]	1.68 (0.41, 6.91)	
			P-value	0.4753	
			Test for interaction[b]	0.7427	
Infections and infestations	Overall	Prior AD medications: Systemic Agents	N	172	176
			n (%)	35 (20.3)	37 (21.0)
			95% CI[a]	(14.33, 26.37)	(15.00, 27.04)
			Relative Risk (95% CI)[a]	0.97 (0.64, 1.46)	
			P-value	0.8767	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	32 (17.0)	39 (20.6)
			95% CI[a]	(11.65, 22.39)	(14.87, 26.40)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.82 (0.54, 1.26)	
			P-value	0.3708	
			Test for interaction[b]	0.6260	
	COVID-19	Prior AD medications: Systemic Agents	N	172	176
			n (%)	9 (5.2)	4 (2.3)
			95% CI[a]	(1.90, 8.56)	(0.07, 4.47)
			Relative Risk (95% CI)[a]	2.30 (0.72, 7.34)	
			P-value	0.1584	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	6 (3.2)	8 (4.2)
			95% CI[a]	(0.68, 5.70)	(1.36, 7.10)
			Relative Risk (95% CI)[a]	0.75 (0.27, 2.13)	
			P-value	0.5943	
			Test for interaction[b]	0.1569	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Conjunctivitis	Prior AD medications: Systemic Agents	N	172	176
			n (%)	3 (1.7)	17 (9.7)
			95% CI[a]	(0.00, 3.70)	(5.29, 14.02)
			Relative Risk (95% CI)[a]	0.18 (0.05, 0.61)	
			P-value	0.0055	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	5 (2.7)	18 (9.5)
			95% CI[a]	(0.36, 4.96)	(5.34, 13.71)
			Relative Risk (95% CI)[a]	0.28 (0.11, 0.74)	
			P-value	0.0100	
			Test for interaction[b]	0.7727	
	Folliculitis	Prior AD medications: Systemic Agents	N	172	176
			n (%)	6 (3.5)	2 (1.1)
			95% CI[a]	(0.75, 6.23)	(0.00, 2.70)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	3.07 (0.63, 15.00)	
			P-value	0.1658	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	6 (3.2)	1 (0.5)
			95% CI[a]	(0.68, 5.70)	(0.00, 1.56)
			Relative Risk (95% CI)[a]	6.03 (0.73, 49.62)	
			P-value	0.0946	
			Test for interaction[b]	0.8891	
	Herpes simplex	Prior AD medications: Systemic Agents	N	172	176
			n (%)	6 (3.5)	3 (1.7)
			95% CI[a]	(0.75, 6.23)	(0.00, 3.62)
			Relative Risk (95% CI)[a]	2.05 (0.52, 8.05)	
			P-value	0.3055	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	6 (3.2)	2 (1.1)
			95% CI[a]	(0.68, 5.70)	(0.00, 2.52)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	3.02 (0.62, 14.75)	
			P-value	0.1729	
			Test for interaction[b]	0.8809	
	Nasopharyngitis	Prior AD medications: Systemic Agents	N	172	176
			n (%)	6 (3.5)	4 (2.3)
			95% CI[a]	(0.75, 6.23)	(0.07, 4.47)
			Relative Risk (95% CI)[a]	1.53 (0.44, 5.34)	
			P-value	0.5009	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	7 (3.7)	8 (4.2)
			95% CI[a]	(1.02, 6.43)	(1.36, 7.10)
			Relative Risk (95% CI)[a]	0.88 (0.33, 2.38)	
			P-value	0.8004	
			Test for interaction[b]	0.5239	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Oral herpes	Prior AD medications: Systemic Agents	N	172	176
			n (%)	5 (2.9)	11 (6.3)
			95% CI[a]	(0.40, 5.42)	(2.67, 9.83)
			Relative Risk (95% CI)[a]	0.47 (0.17, 1.31)	
			P-value	0.1476	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	4 (2.1)	4 (2.1)
			95% CI[a]	(0.06, 4.19)	(0.06, 4.17)
			Relative Risk (95% CI)[a]	1.01 (0.26, 3.96)	
			P-value	0.9939	
			Test for interaction[b]	0.2090	
	Upper respiratory tract infection	Prior AD medications: Systemic Agents	N	172	176
			n (%)	5 (2.9)	2 (1.1)
			95% CI[a]	(0.40, 5.42)	(0.00, 2.70)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.56 (0.50, 13.01)	
			P-value	0.2576	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	5 (2.7)	7 (3.7)
			95% CI[a]	(0.36, 4.96)	(1.01, 6.40)
			Relative Risk (95% CI)[a]	0.72 (0.23, 2.22)	
			P-value	0.5656	
			Test for interaction[b]	0.2341	
Investigations	Overall	Prior AD medications: Systemic Agents	N	172	176
			n (%)	18 (10.5)	9 (5.1)
			95% CI[a]	(5.89, 15.04)	(1.86, 8.37)
			Relative Risk (95% CI)[a]	2.05 (0.95, 4.43)	
			P-value	0.0691	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	20 (10.6)	17 (9.0)
			95% CI[a]	(6.23, 15.05)	(4.92, 13.07)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.18 (0.64, 2.19)	
			P-value	0.5923	
			Test for interaction[b]	0.3895	
	Blood creatine phosphokinase increased	Prior AD medications: Systemic Agents	N	172	176
			n (%)	7 (4.1)	4 (2.3)
			95% CI[a]	(1.12, 7.02)	(0.07, 4.47)
			Relative Risk (95% CI)[a]	1.79 (0.53, 6.01)	
			P-value	0.3455	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	7 (3.7)	9 (4.8)
			95% CI[a]	(1.02, 6.43)	(1.73, 7.80)
			Relative Risk (95% CI)[a]	0.78 (0.30, 2.06)	
			P-value	0.6180	
			Test for interaction[b]	0.3129	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Natural killer cell count decreased	Prior AD medications: Systemic Agents	N	172	176
			n (%)	3 (1.7)	0
			95% CI[a]	(0.00, 3.70)	(0.00, 2.07)
			Relative Risk (95% CI)[a]	6.16 (0.31, 122.01)	
			P-value	0.2329	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	7 (3.7)	0
			95% CI[a]	(1.02, 6.43)	(0.00, 1.93)
			Relative Risk (95% CI)[a]	14.11 (0.81, 246.90)	
			P-value	0.0699	
			Test for interaction[b]	0.2645	
	SARS-CoV-2 test positive	Prior AD medications: Systemic Agents	N	172	176
			n (%)	8 (4.7)	5 (2.8)
			95% CI[a]	(1.50, 7.80)	(0.39, 5.30)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.64 (0.55, 4.91)	
			P-value	0.3786	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	7 (3.7)	8 (4.2)
			95% CI[a]	(1.02, 6.43)	(1.36, 7.10)
			Relative Risk (95% CI)[a]	0.88 (0.33, 2.38)	
			P-value	0.8004	
			Test for interaction[b]	0.4188	
Nervous system disorders	Overall	Prior AD medications: Systemic Agents	N	172	176
			n (%)	29 (16.9)	13 (7.4)
			95% CI[a]	(11.27, 22.46)	(3.52, 11.25)
			Relative Risk (95% CI)[a]	2.28 (1.23, 4.24)	
			P-value	0.0090	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	26 (13.8)	14 (7.4)
			95% CI[a]	(8.90, 18.76)	(3.67, 11.14)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.87 (1.01, 3.46)	
			P-value	0.0475	
			Test for interaction[b]	0.5041	
	Dizziness	Prior AD medications: Systemic Agents	N	172	176
			n (%)	8 (4.7)	3 (1.7)
			95% CI[a]	(1.50, 7.80)	(0.00, 3.62)
			Relative Risk (95% CI)[a]	2.73 (0.74, 10.11)	
			P-value	0.1332	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	2 (1.1)	1 (0.5)
			95% CI[a]	(0.00, 2.53)	(0.00, 1.56)
			Relative Risk (95% CI)[a]	2.01 (0.18, 21.99)	
			P-value	0.5671	
			Test for interaction[b]	0.2467	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Headache	Prior AD medications: Systemic Agents	N	172	176
			n (%)	22 (12.8)	11 (6.3)
			95% CI[a]	(7.80, 17.78)	(2.67, 9.83)
			Relative Risk (95% CI)[a]	2.05 (1.02, 4.09)	
			P-value	0.0427	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	25 (13.3)	13 (6.9)
			95% CI[a]	(8.44, 18.15)	(3.27, 10.49)
			Relative Risk (95% CI)[a]	1.93 (1.02, 3.66)	
			P-value	0.0432	
			Test for interaction[b]	0.9856	
Skin and subcutaneous tissue disorders	Overall	Prior AD medications: Systemic Agents	N	172	176
			n (%)	31 (18.0)	11 (6.3)
			95% CI[a]	(12.28, 23.77)	(2.67, 9.83)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.88 (1.50, 5.55)	
			P-value	0.0015	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	30 (16.0)	12 (6.3)
			95% CI[a]	(10.72, 21.19)	(2.87, 9.83)
			Relative Risk (95% CI)[a]	2.51 (1.33, 4.76)	
			P-value	0.0047	
			Test for interaction[b]	0.6371	
	Acne	Prior AD medications: Systemic Agents	N	172	176
			n (%)	22 (12.8)	4 (2.3)
			95% CI[a]	(7.80, 17.78)	(0.07, 4.47)
			Relative Risk (95% CI)[a]	5.63 (1.98, 15.99)	
			P-value	0.0012	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	24 (12.8)	6 (3.2)
			95% CI[a]	(8.00, 17.54)	(0.68, 5.67)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	4.02 (1.68, 9.61)	
			P-value	0.0018	
			Test for interaction[b]	0.8281	
	Dermatitis atopic	Prior AD medications: Systemic Agents	N	172	176
			n (%)	11 (6.4)	7 (4.0)
			95% CI[a]	(2.74, 10.05)	(1.09, 6.86)
			Relative Risk (95% CI)[a]	1.61 (0.64, 4.05)	
			P-value	0.3137	
		Prior AD medications: Topical Agents Only	N	188	189
			n (%)	6 (3.2)	7 (3.7)
			95% CI[a]	(0.68, 5.70)	(1.01, 6.40)
			Relative Risk (95% CI)[a]	0.86 (0.30, 2.52)	
			P-value	0.7854	
			Test for interaction[b]	0.3327	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Overall	Overall	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	49 (59.0)	38 (36.2)
			95% CI[a]	(48.46, 69.62)	(27.00, 45.38)
			Relative Risk (95% CI)[a]	1.63 (1.20, 2.23)	
			P-value	0.0020	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	145 (52.9)	91 (35.1)
			95% CI[a]	(47.01, 58.83)	(29.32, 40.95)
			Relative Risk (95% CI)[a]	1.51 (1.23, 1.84)	
			P-value	<.0001	
			Test for interaction[b]	0.4707	
		Baseline PP-NRS group: Missing	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Gastrointestinal disorders	Overall	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	17 (20.5)	3 (2.9)
			95% CI[a]	(11.80, 29.16)	(0.00, 6.04)
			Relative Risk (95% CI)[a]	7.17 (2.17, 23.64)	
			P-value	0.0012	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	53 (19.3)	8 (3.1)
			95% CI[a]	(14.67, 24.02)	(0.98, 5.20)
			Relative Risk (95% CI)[a]	6.26 (3.04, 12.91)	
			P-value	<.0001	
			Test for interaction[b]	0.8019	
	Nausea	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	17 (20.5)	2 (1.9)
			95% CI[a]	(11.80, 29.16)	(0.00, 4.52)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	10.75 (2.56, 45.23)	
			P-value	0.0012	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	53 (19.3)	6 (2.3)
			95% CI[a]	(14.67, 24.02)	(0.48, 4.15)
			Relative Risk (95% CI)[a]	8.35 (3.65, 19.09)	
			P-value	<.0001	
			Test for interaction[b]	0.7776	
	Vomiting	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	1 (1.2)	1 (1.0)
			95% CI[a]	(0.00, 3.55)	(0.00, 2.81)
			Relative Risk (95% CI)[a]	1.27 (0.08, 19.92)	
			P-value	0.8672	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	10 (3.6)	5 (1.9)
			95% CI[a]	(1.43, 5.87)	(0.25, 3.61)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.89 (0.65, 5.46)	
			P-value	0.2390	
			Test for interaction[b]	0.4769	
General disorders and administration site conditions	Overall	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	3 (3.6)	0
			95% CI[a]	(0.00, 7.63)	(0.00, 3.45)
			Relative Risk (95% CI)[a]	7.63 (0.39, 150.16)	
			P-value	0.1815	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	7 (2.6)	5 (1.9)
			95% CI[a]	(0.69, 4.42)	(0.25, 3.61)
			Relative Risk (95% CI)[a]	1.32 (0.43, 4.12)	
			P-value	0.6285	
			Test for interaction[b]	0.3207	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Fatigue	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	3 (3.6)	0
			95% CI[a]	(0.00, 7.63)	(0.00, 3.45)
			Relative Risk (95% CI)[a]	7.63 (0.39, 150.16)	
			P-value	0.1815	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	7 (2.6)	5 (1.9)
			95% CI[a]	(0.69, 4.42)	(0.25, 3.61)
			Relative Risk (95% CI)[a]	1.32 (0.43, 4.12)	
			P-value	0.6285	
			Test for interaction[b]	0.3207	
Infections and infestations	Overall	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	25 (30.1)	23 (21.9)
			95% CI[a]	(20.25, 39.99)	(13.99, 29.82)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.38 (0.84, 2.24)	
			P-value	0.2005	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	43 (15.7)	53 (20.5)
			95% CI[a]	(11.39, 20.00)	(15.55, 25.38)
			Relative Risk (95% CI)[a]	0.77 (0.53, 1.10)	
			P-value	0.1537	
			Test for interaction[b]	0.0828	
	COVID-19	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	4 (4.8)	2 (1.9)
			95% CI[a]	(0.21, 9.43)	(0.00, 4.52)
			Relative Risk (95% CI)[a]	2.53 (0.47, 13.48)	
			P-value	0.2768	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	11 (4.0)	10 (3.9)
			95% CI[a]	(1.69, 6.34)	(1.51, 6.21)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.04 (0.45, 2.41)	
			P-value	0.9274	
			Test for interaction[b]	0.3897	
	Conjunctivitis	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	2 (2.4)	13 (12.4)
			95% CI[a]	(0.00, 5.71)	(6.08, 18.68)
			Relative Risk (95% CI)[a]	0.19 (0.05, 0.84)	
			P-value	0.0281	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	6 (2.2)	22 (8.5)
			95% CI[a]	(0.46, 3.92)	(5.10, 11.89)
			Relative Risk (95% CI)[a]	0.26 (0.11, 0.63)	
			P-value	0.0027	
			Test for interaction[b]	0.3673	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Folliculitis	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	8 (9.6)	0
			95% CI[a]	(3.29, 15.99)	(0.00, 3.45)
			Relative Risk (95% CI)[a]	20.34 (1.19, 349.00)	
			P-value	0.0378	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	4 (1.5)	3 (1.2)
			95% CI[a]	(0.04, 2.88)	(0.00, 2.46)
			Relative Risk (95% CI)[a]	1.26 (0.28, 5.58)	
			P-value	0.7604	
			Test for interaction[b]	0.0134	
	Herpes simplex	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	4 (4.8)	1 (1.0)
			95% CI[a]	(0.21, 9.43)	(0.00, 2.81)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	5.06 (0.58, 44.42)	
			P-value	0.1435	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	8 (2.9)	4 (1.5)
			95% CI[a]	(0.93, 4.91)	(0.04, 3.05)
			Relative Risk (95% CI)[a]	1.89 (0.58, 6.20)	
			P-value	0.2935	
			Test for interaction[b]	0.3831	
	Nasopharyngitis	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	4 (4.8)	2 (1.9)
			95% CI[a]	(0.21, 9.43)	(0.00, 4.52)
			Relative Risk (95% CI)[a]	2.53 (0.47, 13.48)	
			P-value	0.2768	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	10 (3.6)	10 (3.9)
			95% CI[a]	(1.43, 5.87)	(1.51, 6.21)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.95 (0.40, 2.23)	
			P-value	0.8979	
			Test for interaction[b]	0.3267	
	Oral herpes	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	4 (4.8)	3 (2.9)
			95% CI[a]	(0.21, 9.43)	(0.00, 6.04)
			Relative Risk (95% CI)[a]	1.69 (0.39, 7.33)	
			P-value	0.4855	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	5 (1.8)	12 (4.6)
			95% CI[a]	(0.24, 3.41)	(2.07, 7.19)
			Relative Risk (95% CI)[a]	0.39 (0.14, 1.10)	
			P-value	0.0760	
			Test for interaction[b]	0.1442	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	Upper respiratory tract infection	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	5 (6.0)	4 (3.8)
			95% CI[a]	(0.91, 11.14)	(0.15, 7.47)
			Relative Risk (95% CI)[a]	1.58 (0.44, 5.70)	
			P-value	0.4838	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	5 (1.8)	5 (1.9)
			95% CI[a]	(0.24, 3.41)	(0.25, 3.61)
			Relative Risk (95% CI)[a]	0.95 (0.28, 3.23)	
			P-value	0.9284	
			Test for interaction[b]	0.4980	
Investigations	Overall	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	9 (10.8)	8 (7.6)
			95% CI[a]	(4.15, 17.53)	(2.54, 12.69)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.42 (0.57, 3.53)	
			P-value	0.4461	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	26 (9.5)	18 (6.9)
			95% CI[a]	(6.02, 12.96)	(3.85, 10.05)
			Relative Risk (95% CI)[a]	1.37 (0.77, 2.43)	
			P-value	0.2897	
			Test for interaction[b]	0.8844	
	Blood creatine phosphokinase increased	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	1 (1.2)	5 (4.8)
			95% CI[a]	(0.00, 3.55)	(0.69, 8.84)
			Relative Risk (95% CI)[a]	0.25 (0.03, 2.12)	
			P-value	0.2055	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	11 (4.0)	8 (3.1)
			95% CI[a]	(1.69, 6.34)	(0.98, 5.20)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.30 (0.53, 3.18)	
			P-value	0.5658	
			Test for interaction[b]	0.1228	
	Natural killer cell count decreased	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	4 (4.8)	0
			95% CI[a]	(0.21, 9.43)	(0.00, 3.45)
			Relative Risk (95% CI)[a]	10.17 (0.55, 189.65)	
			P-value	0.1203	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	6 (2.2)	0
			95% CI[a]	(0.46, 3.92)	(0.00, 1.41)
			Relative Risk (95% CI)[a]	11.36 (0.64, 202.46)	
			P-value	0.0981	
			Test for interaction[b]	0.3706	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
	SARS-CoV-2 test positive	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	4 (4.8)	3 (2.9)
			95% CI[a]	(0.21, 9.43)	(0.00, 6.04)
			Relative Risk (95% CI)[a]	1.69 (0.39, 7.33)	
			P-value	0.4855	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	10 (3.6)	10 (3.9)
			95% CI[a]	(1.43, 5.87)	(1.51, 6.21)
			Relative Risk (95% CI)[a]	0.95 (0.40, 2.23)	
			P-value	0.8979	
			Test for interaction[b]	0.5112	
Nervous system disorders	Overall	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	14 (16.9)	5 (4.8)
			95% CI[a]	(8.81, 24.92)	(0.69, 8.84)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	3.54 (1.33, 9.44)	
			P-value	0.0114	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	41 (15.0)	22 (8.5)
			95% CI[a]	(10.74, 19.19)	(5.10, 11.89)
			Relative Risk (95% CI)[a]	1.76 (1.08, 2.87)	
			P-value	0.0233	
			Test for interaction[b]	0.3173	
	Dizziness	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	1 (1.2)	1 (1.0)
			95% CI[a]	(0.00, 3.55)	(0.00, 2.81)
			Relative Risk (95% CI)[a]	1.27 (0.08, 19.92)	
			P-value	0.8672	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	9 (3.3)	3 (1.2)
			95% CI[a]	(1.17, 5.40)	(0.00, 2.46)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	2.84 (0.78, 10.36)	
			P-value	0.1148	
			Test for interaction[b]	0.3418	
	Headache	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	13 (15.7)	4 (3.8)
			95% CI[a]	(7.84, 23.48)	(0.15, 7.47)
			Relative Risk (95% CI)[a]	4.11 (1.39, 12.14)	
			P-value	0.0105	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	34 (12.4)	20 (7.7)
			95% CI[a]	(8.51, 16.31)	(4.47, 10.97)
			Relative Risk (95% CI)[a]	1.61 (0.95, 2.72)	
			P-value	0.0769	
			Test for interaction[b]	0.1768	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
Skin and subcutaneous tissue disorders	Overall	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	10 (12.0)	6 (5.7)
			95% CI[a]	(5.05, 19.05)	(1.27, 10.15)
			Relative Risk (95% CI)[a]	2.11 (0.80, 5.56)	
			P-value	0.1319	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	51 (18.6)	17 (6.6)
			95% CI[a]	(14.00, 23.22)	(3.55, 9.58)
			Relative Risk (95% CI)[a]	2.84 (1.68, 4.78)	
			P-value	<.0001	
			Test for interaction[b]	0.2353	
	Acne	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	9 (10.8)	1 (1.0)
			95% CI[a]	(4.15, 17.53)	(0.00, 2.81)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	11.39 (1.47, 88.07)	
			P-value	0.0198	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	37 (13.5)	9 (3.5)
			95% CI[a]	(9.46, 17.55)	(1.24, 5.71)
			Relative Risk (95% CI)[a]	3.89 (1.91, 7.89)	
			P-value	0.0002	
			Test for interaction[b]	0.9248	
	Dermatitis atopic	Baseline PP-NRS group: 4-6	N	83	105
			n (%)	1 (1.2)	6 (5.7)
			95% CI[a]	(0.00, 3.55)	(1.27, 10.15)
			Relative Risk (95% CI)[a]	0.21 (0.03, 1.72)	
			P-value	0.1458	
		Baseline PP-NRS group: >=7	N	274	259
			n (%)	16 (5.8)	8 (3.1)
			95% CI[a]	(3.06, 8.62)	(0.98, 5.20)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	**Dupilumab 300mg Q2W (N=365)**
System Organ Class	**MedDRA Preferred Term**	**Subgroup**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	1.89 (0.82, 4.34)	
			P-value	0.1333	
			Test for interaction[b]	0.0212	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Serious Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Table not created
No participant meets the reporting criteria

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_8

Proportion of Subjects with Treatment-Emergent Severe Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Table not created
No participant meets the reporting criteria

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	173 (75.2)	161 (65.2)
			95% CI[a]	(69.64, 80.80)	(59.24, 71.12)
			Relative Risk (95% CI)[a]	1.15 (1.03, 1.30)	
			P-value	0.0169	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	94 (71.2)	76 (64.4)
			95% CI[a]	(63.49, 78.94)	(55.77, 73.05)
			Relative Risk (95% CI)[a]	1.11 (0.93, 1.31)	
			P-value	0.2538	
			Test for interaction[b]	0.5853	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_10_1

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	250 (73.3)	234 (66.1)
			95% CI[a]	(68.62, 78.01)	(61.17, 71.03)
			Relative Risk (95% CI)[a]	1.11 (1.01, 1.22)	
			P-value	0.0390	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	17 (81.0)	3 (27.3)
			95% CI[a]	(64.16, 97.75)	(0.95, 53.59)
			Relative Risk (95% CI)[a]	2.97 (1.11, 7.96)	
			P-value	0.0307	
			Test for interaction[b]	0.0277	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	141 (73.1)	127 (62.3)
			95% CI[a]	(66.80, 79.32)	(55.60, 68.91)
			Relative Risk (95% CI)[a]	1.17 (1.02, 1.35)	
			P-value	0.0220	
Sex: Female	Overall	Overall	N	169	161
			n (%)	126 (74.6)	110 (68.3)
			95% CI[a]	(67.99, 81.12)	(61.14, 75.51)
			Relative Risk (95% CI)[a]	1.09 (0.95, 1.25)	
			P-value	0.2123	
			Test for interaction[b]	0.6078	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	201 (74.7)	167 (67.3)
			95% CI[a]	(69.53, 79.91)	(61.50, 73.18)
			Relative Risk (95% CI)[a]	1.11 (0.99, 1.24)	
			P-value	0.0665	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	16 (64.0)	13 (50.0)
			95% CI[a]	(45.18, 82.82)	(30.78, 69.22)
			Relative Risk (95% CI)[a]	1.28 (0.79, 2.08)	
			P-value	0.3174	
Race: Asian	Overall	Overall	N	62	83
			n (%)	44 (71.0)	52 (62.7)
			95% CI[a]	(59.67, 82.27)	(52.24, 73.06)
			Relative Risk (95% CI)[a]	1.13 (0.90, 1.43)	
			P-value	0.2883	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_10_1

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: Other	Overall	Overall	N	6	8
			n (%)	6 (100.0)	5 (62.5)
			95% CI[a]	(54.07, 100.00)	(28.95, 96.05)
			Relative Risk (95% CI)[a]	1.48 (0.83, 2.64)	
			P-value	0.1882	
			Test for interaction[b]	0.8286	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	133 (75.1)	128 (65.6)
			95% CI[a]	(68.77, 81.51)	(58.98, 72.31)
			Relative Risk (95% CI)[a]	1.14 (1.00, 1.31)	
			P-value	0.0452	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	111 (74.0)	90 (68.2)
			95% CI[a]	(66.98, 81.02)	(60.24, 76.13)
			Relative Risk (95% CI)[a]	1.09 (0.93, 1.26)	
			P-value	0.2855	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	11 (64.7)	10 (52.6)
			95% CI[a]	(41.99, 87.42)	(30.18, 75.08)
			Relative Risk (95% CI)[a]	1.23 (0.71, 2.14)	
			P-value	0.4637	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_10_1

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	12 (66.7)	9 (47.4)
			95% CI[a]	(44.89, 88.44)	(24.92, 69.82)
			Relative Risk (95% CI)[a]	1.41 (0.79, 2.50)	
			P-value	0.2446	
			Test for interaction[b]	0.9324	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	162 (75.0)	146 (66.4)
			95% CI[a]	(69.23, 80.77)	(60.12, 72.61)
			Relative Risk (95% CI)[a]	1.13 (1.00, 1.28)	
			P-value	0.0486	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	105 (71.9)	91 (62.8)
			95% CI[a]	(64.63, 79.21)	(54.89, 70.63)
			Relative Risk (95% CI)[a]	1.15 (0.98, 1.35)	
			P-value	0.0977	
			Test for interaction[b]	0.9495	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	30 (75.0)	29 (56.9)
			95% CI[a]	(61.58, 88.42)	(43.27, 70.46)
			Relative Risk (95% CI)[a]	1.32 (0.98, 1.78)	
			P-value	0.0692	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	237 (73.6)	208 (66.2)
			95% CI[a]	(68.79, 78.42)	(61.01, 71.47)
			Relative Risk (95% CI)[a]	1.11 (1.00, 1.23)	
			P-value	0.0440	
			Test for interaction[b]	0.3786	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_10_1

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	98 (74.2)	90 (66.2)
			95% CI[a]	(66.78, 81.70)	(58.23, 74.13)
			Relative Risk (95% CI)[a]	1.12 (0.96, 1.31)	
			P-value	0.1501	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	143 (73.0)	116 (63.0)
			95% CI[a]	(66.74, 79.18)	(56.07, 70.02)
			Relative Risk (95% CI)[a]	1.16 (1.01, 1.33)	
			P-value	0.0404	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	26 (76.5)	31 (68.9)
			95% CI[a]	(62.21, 90.73)	(55.36, 82.42)
			Relative Risk (95% CI)[a]	1.11 (0.85, 1.46)	
			P-value	0.4498	
			Test for interaction[b]	0.9857	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_10_1

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	158 (71.2)	131 (59.5)
			95% CI[a]	(65.21, 77.13)	(53.06, 66.03)
			Relative Risk (95% CI)[a]	1.20 (1.04, 1.37)	
			P-value	0.0109	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	109 (77.9)	106 (73.1)
			95% CI[a]	(70.98, 84.73)	(65.89, 80.32)
			Relative Risk (95% CI)[a]	1.07 (0.93, 1.22)	
			P-value	0.3513	
			Test for interaction[b]	0.5611	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	138 (76.2)	126 (68.9)
			95% CI[a]	(70.04, 82.44)	(62.14, 75.56)
			Relative Risk (95% CI)[a]	1.11 (0.98, 1.26)	
			P-value	0.1154	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	121 (70.3)	104 (59.8)
			95% CI[a]	(63.52, 77.17)	(52.48, 67.06)
			Relative Risk (95% CI)[a]	1.18 (1.01, 1.38)	
			P-value	0.0404	
			Test for interaction[b]	0.8808	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_10_1

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	89 (73.0)	91 (68.4)
			95% CI[a]	(65.07, 80.83)	(60.52, 76.32)
			Relative Risk (95% CI)[a]	1.07 (0.91, 1.25)	
			P-value	0.4269	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	97 (73.5)	79 (65.3)
			95% CI[a]	(65.95, 81.02)	(56.81, 73.77)
			Relative Risk (95% CI)[a]	1.13 (0.95, 1.33)	
			P-value	0.1613	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	81 (75.0)	67 (60.4)
			95% CI[a]	(66.83, 83.17)	(51.26, 69.46)
			Relative Risk (95% CI)[a]	1.24 (1.03, 1.50)	
			P-value	0.0221	
			Test for interaction[b]	0.5511	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_10_1

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	131 (76.2)	118 (67.0)
			95% CI[a]	(69.80, 82.53)	(60.10, 73.99)
			Relative Risk (95% CI)[a]	1.14 (0.99, 1.30)	
			P-value	0.0605	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	135 (71.8)	119 (63.0)
			95% CI[a]	(65.38, 78.24)	(56.08, 69.85)
			Relative Risk (95% CI)[a]	1.14 (0.99, 1.31)	
			P-value	0.0683	
			Test for interaction[b]	0.8242	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.7 Abrocitinib
Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	64 (77.1)	71 (67.6)
			95% CI[a]	(68.07, 86.15)	(58.67, 76.57)
			Relative Risk (95% CI)[a]	1.14 (0.96, 1.36)	
			P-value	0.1455	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	200 (73.0)	165 (63.7)
			95% CI[a]	(67.74, 78.25)	(57.85, 69.56)
			Relative Risk (95% CI)[a]	1.15 (1.02, 1.29)	
			P-value	0.0224	
			Test for interaction[b]	0.8535	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	19 (8.3)	15 (6.1)
			95% CI[a]	(4.70, 11.82)	(3.09, 9.05)
			Relative Risk (95% CI)[a]	1.36 (0.71, 2.61)	
			P-value	0.3555	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	12 (9.1)	7 (5.9)
			95% CI[a]	(4.19, 14.00)	(1.67, 10.19)
			Relative Risk (95% CI)[a]	1.53 (0.62, 3.76)	
			P-value	0.3517	
			Test for interaction[b]	0.8103	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	29 (8.5)	22 (6.2)
			95% CI[a]	(5.54, 11.47)	(3.70, 8.73)
			Relative Risk (95% CI)[a]	1.37 (0.80, 2.33)	
			P-value	0.2495	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	2 (9.5)	0
			95% CI[a]	(0.00, 22.08)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	2.19 (0.11, 44.64)	
			P-value	0.6102	
			Test for interaction[b]	0.7502	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	19 (9.8)	12 (5.9)
			95% CI[a]	(5.64, 14.05)	(2.65, 9.11)
			Relative Risk (95% CI)[a]	1.67 (0.83, 3.35)	
			P-value	0.1467	
Sex: Female	Overall	Overall	N	169	161
			n (%)	12 (7.1)	10 (6.2)
			95% CI[a]	(3.23, 10.97)	(2.48, 9.94)
			Relative Risk (95% CI)[a]	1.14 (0.51, 2.57)	
			P-value	0.7464	
			Test for interaction[b]	0.4216	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	25 (9.3)	19 (7.7)
			95% CI[a]	(5.82, 12.76)	(4.35, 10.97)
			Relative Risk (95% CI)[a]	1.21 (0.69, 2.15)	
			P-value	0.5073	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	1 (4.0)	0
			95% CI[a]	(0.00, 11.68)	(0.00, 13.23)
			Relative Risk (95% CI)[a]	2.12 (0.07, 60.46)	
			P-value	0.6603	
Race: Asian	Overall	Overall	N	62	83
			n (%)	4 (6.5)	1 (1.2)
			95% CI[a]	(0.34, 12.57)	(0.00, 3.55)
			Relative Risk (95% CI)[a]	5.35 (0.61, 46.73)	
			P-value	0.1290	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: Other	Overall	Overall	N	6	8
			n (%)	1 (16.7)	2 (25.0)
			95% CI[a]	(0.00, 46.49)	(0.00, 55.01)
			Relative Risk (95% CI)[a]	0.67 (0.08, 5.75)	
			P-value	0.7122	
			Test for interaction[b]	0.8119	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	14 (7.9)	11 (5.6)
			95% CI[a]	(3.93, 11.89)	(2.40, 8.88)
			Relative Risk (95% CI)[a]	1.40 (0.65, 3.01)	
			P-value	0.3853	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	15 (10.0)	11 (8.3)
			95% CI[a]	(5.20, 14.80)	(3.62, 13.05)
			Relative Risk (95% CI)[a]	1.20 (0.57, 2.52)	
			P-value	0.6301	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	1 (5.9)	0
			95% CI[a]	(0.00, 17.07)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.29 (0.08, 64.21)	
			P-value	0.6252	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	1 (5.6)	0
			95% CI[a]	(0.00, 16.14)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.17 (0.08, 60.76)	
			P-value	0.6494	
			Test for interaction[b]	0.9965	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	18 (8.3)	11 (5.0)
			95% CI[a]	(4.65, 12.02)	(2.12, 7.88)
			Relative Risk (95% CI)[a]	1.67 (0.81, 3.45)	
			P-value	0.1680	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	13 (8.9)	11 (7.6)
			95% CI[a]	(4.28, 13.52)	(3.28, 11.90)
			Relative Risk (95% CI)[a]	1.17 (0.54, 2.53)	
			P-value	0.6832	
			Test for interaction[b]	0.6238	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	2 (5.0)	0
			95% CI[a]	(0.00, 11.75)	(0.00, 6.98)
			Relative Risk (95% CI)[a]	5.15 (0.24, 111.09)	
			P-value	0.2956	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	29 (9.0)	22 (7.0)
			95% CI[a]	(5.88, 12.13)	(4.18, 9.83)
			Relative Risk (95% CI)[a]	1.29 (0.76, 2.19)	
			P-value	0.3548	
			Test for interaction[b]	0.6622	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	11 (8.3)	12 (8.8)
			95% CI[a]	(3.62, 13.05)	(4.06, 13.59)
			Relative Risk (95% CI)[a]	0.94 (0.43, 2.07)	
			P-value	0.8861	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	20 (10.2)	8 (4.3)
			95% CI[a]	(5.97, 14.44)	(1.40, 7.29)
			Relative Risk (95% CI)[a]	2.35 (1.06, 5.20)	
			P-value	0.0354	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	0	2 (4.4)
			95% CI[a]	(0.00, 10.28)	(0.00, 10.47)
			Relative Risk (95% CI)[a]	0.33 (0.02, 7.00)	
			P-value	0.4739	
			Test for interaction[b]	0.1061	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	17 (7.7)	8 (3.6)
			95% CI[a]	(4.16, 11.16)	(1.16, 6.11)
			Relative Risk (95% CI)[a]	2.11 (0.93, 4.78)	
			P-value	0.0749	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	14 (10.0)	14 (9.7)
			95% CI[a]	(5.03, 14.97)	(4.85, 14.46)
			Relative Risk (95% CI)[a]	1.04 (0.51, 2.09)	
			P-value	0.9221	
			Test for interaction[b]	0.3944	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	15 (8.3)	7 (3.8)
			95% CI[a]	(4.27, 12.30)	(1.05, 6.60)
			Relative Risk (95% CI)[a]	2.17 (0.90, 5.19)	
			P-value	0.0827	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	14 (8.1)	15 (8.6)
			95% CI[a]	(4.05, 12.23)	(4.45, 12.79)
			Relative Risk (95% CI)[a]	0.94 (0.47, 1.90)	
			P-value	0.8717	
			Test for interaction[b]	0.2103	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	9 (7.4)	3 (2.3)
			95% CI[a]	(2.74, 12.02)	(0.00, 4.78)
			Relative Risk (95% CI)[a]	3.27 (0.91, 11.80)	
			P-value	0.0703	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	11 (8.3)	6 (5.0)
			95% CI[a]	(3.62, 13.05)	(1.09, 8.83)
			Relative Risk (95% CI)[a]	1.68 (0.64, 4.41)	
			P-value	0.2910	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	11 (10.2)	13 (11.7)
			95% CI[a]	(4.48, 15.89)	(5.73, 17.69)
			Relative Risk (95% CI)[a]	0.87 (0.41, 1.86)	
			P-value	0.7180	
			Test for interaction[b]	0.4403	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	13 (7.6)	13 (7.4)
			95% CI[a]	(3.61, 11.51)	(3.52, 11.25)
			Relative Risk (95% CI)[a]	1.02 (0.49, 2.14)	
			P-value	0.9514	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	18 (9.6)	9 (4.8)
			95% CI[a]	(5.37, 13.78)	(1.73, 7.80)
			Relative Risk (95% CI)[a]	2.01 (0.93, 4.36)	
			P-value	0.0771	
			Test for interaction[b]	0.2329	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	11 (13.3)	6 (5.7)
			95% CI[a]	(5.96, 20.55)	(1.27, 10.15)
			Relative Risk (95% CI)[a]	2.32 (0.90, 6.01)	
			P-value	0.0833	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	20 (7.3)	16 (6.2)
			95% CI[a]	(4.22, 10.38)	(3.25, 9.11)
			Relative Risk (95% CI)[a]	1.18 (0.63, 2.23)	
			P-value	0.6066	
			Test for interaction[b]	0.1899	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	4 (1.7)	1 (0.4)
			95% CI[a]	(0.05, 3.43)	(0.00, 1.20)
			Relative Risk (95% CI)[a]	4.30 (0.48, 38.15)	
			P-value	0.1908	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	5 (3.8)	1 (0.8)
			95% CI[a]	(0.53, 7.04)	(0.00, 2.50)
			Relative Risk (95% CI)[a]	4.47 (0.53, 37.71)	
			P-value	0.1688	
			Test for interaction[b]	0.4405	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	7 (2.1)	2 (0.6)
			95% CI[a]	(0.55, 3.56)	(0.00, 1.35)
			Relative Risk (95% CI)[a]	3.63 (0.76, 17.37)	
			P-value	0.1060	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	2 (9.5)	0
			95% CI[a]	(0.00, 22.08)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	2.19 (0.11, 44.64)	
			P-value	0.6102	
			Test for interaction[b]	0.6698	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	5 (2.6)	1 (0.5)
			95% CI[a]	(0.35, 4.83)	(0.00, 1.45)
			Relative Risk (95% CI)[a]	5.28 (0.62, 44.83)	
			P-value	0.1270	
Sex: Female	Overall	Overall	N	169	161
			n (%)	4 (2.4)	1 (0.6)
			95% CI[a]	(0.07, 4.66)	(0.00, 1.83)
			Relative Risk (95% CI)[a]	3.81 (0.43, 33.73)	
			P-value	0.2292	
			Test for interaction[b]	0.8457	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	8 (3.0)	2 (0.8)
			95% CI[a]	(0.94, 5.00)	(0.00, 1.92)
			Relative Risk (95% CI)[a]	3.69 (0.79, 17.20)	
			P-value	0.0967	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	1 (4.0)	0
			95% CI[a]	(0.00, 11.68)	(0.00, 13.23)
			Relative Risk (95% CI)[a]	2.12 (0.07, 60.46)	
			P-value	0.6603	
Race: Asian	Overall	Overall	N	62	83
			n (%)	0	0
Race: Other	Overall	Overall	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.7564	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13

Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	5 (2.8)	1 (0.5)
			95% CI[a]	(0.38, 5.27)	(0.00, 1.52)
			Relative Risk (95% CI)[a]	5.51 (0.65, 46.70)	
			P-value	0.1177	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	4 (2.7)	1 (0.8)
			95% CI[a]	(0.09, 5.24)	(0.00, 2.24)
			Relative Risk (95% CI)[a]	3.52 (0.40, 31.10)	
			P-value	0.2576	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	0	0
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9636	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13

Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	4 (1.9)	2 (0.9)
			95% CI[a]	(0.05, 3.65)	(0.00, 2.16)
			Relative Risk (95% CI)[a]	2.04 (0.38, 11.01)	
			P-value	0.4084	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	5 (3.4)	0
			95% CI[a]	(0.47, 6.37)	(0.00, 2.51)
			Relative Risk (95% CI)[a]	9.97 (0.55, 180.76)	
			P-value	0.1200	
			Test for interaction[b]	0.2721	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13

Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	2 (5.0)	0
			95% CI[a]	(0.00, 11.75)	(0.00, 6.98)
			Relative Risk (95% CI)[a]	5.15 (0.24, 111.09)	
			P-value	0.2956	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	7 (2.2)	2 (0.6)
			95% CI[a]	(0.58, 3.77)	(0.00, 1.52)
			Relative Risk (95% CI)[a]	3.41 (0.71, 16.30)	
			P-value	0.1239	
			Test for interaction[b]	0.5160	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13

Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	6 (4.5)	1 (0.7)
			95% CI[a]	(0.99, 8.10)	(0.00, 2.17)
			Relative Risk (95% CI)[a]	6.18 (0.75, 50.65)	
			P-value	0.0896	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	3 (1.5)	1 (0.5)
			95% CI[a]	(0.00, 3.25)	(0.00, 1.61)
			Relative Risk (95% CI)[a]	2.82 (0.30, 26.83)	
			P-value	0.3680	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	0	0
			Test for interaction[b]	0.4008	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	4 (1.8)	1 (0.5)
			95% CI[a]	(0.05, 3.55)	(0.00, 1.34)
			Relative Risk (95% CI)[a]	3.96 (0.45, 35.18)	
			P-value	0.2163	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	5 (3.6)	1 (0.7)
			95% CI[a]	(0.50, 6.65)	(0.00, 2.04)
			Relative Risk (95% CI)[a]	5.18 (0.61, 43.77)	
			P-value	0.1310	
			Test for interaction[b]	0.4379	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13

Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	3 (1.7)	2 (1.1)
			95% CI[a]	(0.00, 3.52)	(0.00, 2.60)
			Relative Risk (95% CI)[a]	1.52 (0.26, 8.97)	
			P-value	0.6461	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	6 (3.5)	0
			95% CI[a]	(0.75, 6.23)	(0.00, 2.10)
			Relative Risk (95% CI)[a]	12.17 (0.69, 216.29)	
			P-value	0.0887	
			Test for interaction[b]	0.1675	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	1 (0.8)	0
			95% CI[a]	(0.00, 2.42)	(0.00, 2.74)
			Relative Risk (95% CI)[a]	2.19 (0.07, 64.66)	
			P-value	0.6503	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	4 (3.0)	2 (1.7)
			95% CI[a]	(0.11, 5.95)	(0.00, 3.92)
			Relative Risk (95% CI)[a]	1.83 (0.34, 9.83)	
			P-value	0.4793	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	4 (3.7)	0
			95% CI[a]	(0.14, 7.27)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	8.26 (0.44, 154.37)	
			P-value	0.1576	
			Test for interaction[b]	0.4239	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	5 (2.9)	2 (1.1)
			95% CI[a]	(0.40, 5.42)	(0.00, 2.70)
			Relative Risk (95% CI)[a]	2.56 (0.50, 13.01)	
			P-value	0.2576	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	4 (2.1)	0
			95% CI[a]	(0.06, 4.19)	(0.00, 1.93)
			Relative Risk (95% CI)[a]	8.06 (0.43, 151.47)	
			P-value	0.1631	
			Test for interaction[b]	0.9671	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.1 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	0	1 (1.0)
			95% CI[a]	(0.00, 4.35)	(0.00, 2.81)
			Relative Risk (95% CI)[a]	0.63 (0.02, 18.51)	
			P-value	0.7880	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	9 (3.3)	1 (0.4)
			95% CI[a]	(1.17, 5.40)	(0.00, 1.14)
			Relative Risk (95% CI)[a]	8.51 (1.09, 66.68)	
			P-value	0.0416	
			Test for interaction[b]	0.0571	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	34 (14.8)	10 (4.0)
			95% CI[a]	(10.20, 19.37)	(1.59, 6.51)
			Relative Risk (95% CI)[a]	3.65 (1.85, 7.22)	
			P-value	0.0002	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	14 (10.6)	1 (0.8)
			95% CI[a]	(5.35, 15.86)	(0.00, 2.50)
			Relative Risk (95% CI)[a]	12.52 (1.67, 93.73)	
			P-value	0.0139	
			Test for interaction[b]	0.7300	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	48 (14.1)	11 (3.1)
			95% CI[a]	(10.39, 17.77)	(1.30, 4.91)
			Relative Risk (95% CI)[a]	4.53 (2.39, 8.57)	
			P-value	<.0001	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	0	0
			Test for interaction[b]	NE	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	26 (13.5)	4 (2.0)
			95% CI[a]	(8.65, 18.29)	(0.06, 3.86)
			Relative Risk (95% CI)[a]	6.87 (2.44, 19.32)	
			P-value	0.0003	
Sex: Female	Overall	Overall	N	169	161
			n (%)	22 (13.0)	7 (4.3)
			95% CI[a]	(7.94, 18.09)	(1.20, 7.50)
			Relative Risk (95% CI)[a]	2.99 (1.32, 6.82)	
			P-value	0.0090	
			Test for interaction[b]	0.5116	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	28 (10.4)	5 (2.0)
			95% CI[a]	(6.76, 14.06)	(0.27, 3.77)
			Relative Risk (95% CI)[a]	5.16 (2.03, 13.16)	
			P-value	0.0006	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	2 (8.0)	1 (3.8)
			95% CI[a]	(0.00, 18.63)	(0.00, 11.24)
			Relative Risk (95% CI)[a]	2.08 (0.20, 21.52)	
			P-value	0.5390	
Race: Asian	Overall	Overall	N	62	83
			n (%)	15 (24.2)	4 (4.8)
			95% CI[a]	(13.53, 34.85)	(0.21, 9.43)
			Relative Risk (95% CI)[a]	5.02 (1.75, 14.38)	
			P-value	0.0027	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:26)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_1

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: Other	Overall	Overall	N	6	8
			n (%)	3 (50.0)	1 (12.5)
			95% CI[a]	(9.99, 90.01)	(0.00, 35.42)
			Relative Risk (95% CI)[a]	4.00 (0.54, 29.57)	
			P-value	0.1744	
			Test for interaction[b]	0.1881	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	30 (16.9)	8 (4.1)
			95% CI[a]	(11.42, 22.48)	(1.32, 6.89)
			Relative Risk (95% CI)[a]	4.13 (1.95, 8.77)	
			P-value	0.0002	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	14 (9.3)	1 (0.8)
			95% CI[a]	(4.68, 13.99)	(0.00, 2.24)
			Relative Risk (95% CI)[a]	12.32 (1.64, 92.43)	
			P-value	0.0146	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	4 (23.5)	2 (10.5)
			95% CI[a]	(3.37, 43.69)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	2.24 (0.47, 10.70)	
			P-value	0.3141	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.1721	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	30 (13.9)	3 (1.4)
			95% CI[a]	(9.28, 18.50)	(0.00, 2.90)
			Relative Risk (95% CI)[a]	10.19 (3.16, 32.88)	
			P-value	0.0001	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	18 (12.3)	8 (5.5)
			95% CI[a]	(7.00, 17.66)	(1.80, 9.23)
			Relative Risk (95% CI)[a]	2.23 (1.00, 4.98)	
			P-value	0.0490	
			Test for interaction[b]	0.1911	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:26)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_1

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	4 (10.0)	0
			95% CI[a]	(0.70, 19.30)	(0.00, 6.98)
			Relative Risk (95% CI)[a]	10.30 (0.56, 189.22)	
			P-value	0.1163	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	44 (13.7)	11 (3.5)
			95% CI[a]	(9.91, 17.42)	(1.47, 5.54)
			Relative Risk (95% CI)[a]	3.90 (2.05, 7.41)	
			P-value	<.0001	
			Test for interaction[b]	0.7933	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:26)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_1

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	19 (14.4)	4 (2.9)
			95% CI[a]	(8.41, 20.38)	(0.10, 5.78)
			Relative Risk (95% CI)[a]	4.89 (1.71, 14.00)	
			P-value	0.0031	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	25 (12.8)	7 (3.8)
			95% CI[a]	(8.08, 17.43)	(1.04, 6.57)
			Relative Risk (95% CI)[a]	3.35 (1.49, 7.56)	
			P-value	0.0036	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	4 (11.8)	0
			95% CI[a]	(0.93, 22.59)	(0.00, 7.87)
			Relative Risk (95% CI)[a]	10.71 (0.59, 195.78)	
			P-value	0.1098	
			Test for interaction[b]	0.8508	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:26)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_1

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	24 (10.8)	7 (3.2)
			95% CI[a]	(6.73, 14.90)	(0.86, 5.50)
			Relative Risk (95% CI)[a]	3.40 (1.49, 7.72)	
			P-value	0.0035	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	24 (17.1)	4 (2.8)
			95% CI[a]	(10.90, 23.39)	(0.09, 5.42)
			Relative Risk (95% CI)[a]	6.21 (2.21, 17.45)	
			P-value	0.0005	
			Test for interaction[b]	0.1090	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:26)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_1

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	26 (14.4)	7 (3.8)
			95% CI[a]	(9.26, 19.47)	(1.05, 6.60)
			Relative Risk (95% CI)[a]	3.76 (1.67, 8.43)	
			P-value	0.0013	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	20 (11.6)	4 (2.3)
			95% CI[a]	(6.84, 16.42)	(0.07, 4.53)
			Relative Risk (95% CI)[a]	5.06 (1.77, 14.49)	
			P-value	0.0025	
			Test for interaction[b]	0.7282	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	13 (10.7)	2 (1.5)
			95% CI[a]	(5.18, 16.13)	(0.00, 3.57)
			Relative Risk (95% CI)[a]	7.09 (1.63, 30.77)	
			P-value	0.0090	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	17 (12.9)	6 (5.0)
			95% CI[a]	(7.16, 18.59)	(1.09, 8.83)
			Relative Risk (95% CI)[a]	2.60 (1.06, 6.37)	
			P-value	0.0371	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	18 (16.7)	3 (2.7)
			95% CI[a]	(9.64, 23.70)	(0.00, 5.72)
			Relative Risk (95% CI)[a]	6.17 (1.87, 20.34)	
			P-value	0.0028	
			Test for interaction[b]	0.4888	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:26)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_1

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	23 (13.4)	4 (2.3)
			95% CI[a]	(8.29, 18.46)	(0.07, 4.47)
			Relative Risk (95% CI)[a]	5.88 (2.08, 16.66)	
			P-value	0.0008	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	25 (13.3)	7 (3.7)
			95% CI[a]	(8.44, 18.15)	(1.01, 6.40)
			Relative Risk (95% CI)[a]	3.59 (1.59, 8.10)	
			P-value	0.0021	
			Test for interaction[b]	0.7302	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.2 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	11 (13.3)	2 (1.9)
			95% CI[a]	(5.96, 20.55)	(0.00, 4.52)
			Relative Risk (95% CI)[a]	6.96 (1.59, 30.53)	
			P-value	0.0101	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	37 (13.5)	9 (3.5)
			95% CI[a]	(9.46, 17.55)	(1.24, 5.71)
			Relative Risk (95% CI)[a]	3.89 (1.91, 7.89)	
			P-value	0.0002	
			Test for interaction[b]	0.8001	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	7 (3.0)	2 (0.8)
			95% CI[a]	(0.82, 5.26)	(0.00, 1.93)
			Relative Risk (95% CI)[a]	3.76 (0.79, 17.91)	
			P-value	0.0965	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	4 (3.0)	1 (0.8)
			95% CI[a]	(0.11, 5.95)	(0.00, 2.50)
			Relative Risk (95% CI)[a]	3.58 (0.41, 31.54)	
			P-value	0.2514	
			Test for interaction[b]	0.9812	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	10 (2.9)	3 (0.8)
			95% CI[a]	(1.14, 4.72)	(0.00, 1.80)
			Relative Risk (95% CI)[a]	3.46 (0.96, 12.47)	
			P-value	0.0576	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.8331	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	9 (4.7)	2 (1.0)
			95% CI[a]	(1.69, 7.64)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	4.76 (1.04, 21.74)	
			P-value	0.0443	
Sex: Female	Overall	Overall	N	169	161
			n (%)	2 (1.2)	1 (0.6)
			95% CI[a]	(0.00, 2.81)	(0.00, 1.83)
			Relative Risk (95% CI)[a]	1.91 (0.17, 20.81)	
			P-value	0.5972	
			Test for interaction[b]	0.1122	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_2

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	9 (3.3)	0
			95% CI[a]	(1.20, 5.49)	(0.00, 1.48)
			Relative Risk (95% CI)[a]	16.63 (0.97, 285.33)	
			P-value	0.0526	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	0	1 (3.8)
			95% CI[a]	(0.00, 13.72)	(0.00, 11.24)
			Relative Risk (95% CI)[a]	0.51 (0.02, 14.54)	
			P-value	0.6935	
Race: Asian	Overall	Overall	N	62	83
			n (%)	2 (3.2)	2 (2.4)
			95% CI[a]	(0.00, 7.62)	(0.00, 5.71)
			Relative Risk (95% CI)[a]	1.34 (0.19, 9.24)	
			P-value	0.7673	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: Other	Overall	Overall	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.6766	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	4 (2.3)	3 (1.5)
			95% CI[a]	(0.07, 4.45)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	1.47 (0.33, 6.47)	
			P-value	0.6113	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	5 (3.3)	0
			95% CI[a]	(0.46, 6.21)	(0.00, 2.76)
			Relative Risk (95% CI)[a]	8.83 (0.49, 160.17)	
			P-value	0.1406	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	2 (11.8)	0
			95% CI[a]	(0.00, 27.08)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	4.59 (0.22, 94.96)	
			P-value	0.3244	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.5893	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	8 (3.7)	1 (0.5)
			95% CI[a]	(1.19, 6.22)	(0.00, 1.34)
			Relative Risk (95% CI)[a]	8.15 (1.03, 64.60)	
			P-value	0.0470	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	3 (2.1)	2 (1.4)
			95% CI[a]	(0.00, 4.36)	(0.00, 3.28)
			Relative Risk (95% CI)[a]	1.49 (0.25, 8.78)	
			P-value	0.6597	
			Test for interaction[b]	0.2092	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_2

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	1 (2.5)	0
			95% CI[a]	(0.00, 7.34)	(0.00, 6.98)
			Relative Risk (95% CI)[a]	2.58 (0.09, 74.84)	
			P-value	0.5822	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	10 (3.1)	3 (1.0)
			95% CI[a]	(1.21, 5.00)	(0.00, 2.03)
			Relative Risk (95% CI)[a]	3.25 (0.90, 11.70)	
			P-value	0.0712	
			Test for interaction[b]	0.8368	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_2

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	2 (1.5)	2 (1.5)
			95% CI[a]	(0.00, 3.60)	(0.00, 3.49)
			Relative Risk (95% CI)[a]	1.03 (0.15, 7.21)	
			P-value	0.9760	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	9 (4.6)	1 (0.5)
			95% CI[a]	(1.66, 7.52)	(0.00, 1.61)
			Relative Risk (95% CI)[a]	8.45 (1.08, 66.04)	
			P-value	0.0419	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	0	0
			Test for interaction[b]	0.1597	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_2

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	6 (2.7)	0
			95% CI[a]	(0.57, 4.84)	(0.00, 1.66)
			Relative Risk (95% CI)[a]	11.92 (0.67, 212.11)	
			P-value	0.0916	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	5 (3.6)	3 (2.1)
			95% CI[a]	(0.50, 6.65)	(0.00, 4.39)
			Relative Risk (95% CI)[a]	1.73 (0.42, 7.09)	
			P-value	0.4487	
			Test for interaction[b]	0.6790	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	7 (3.9)	1 (0.5)
			95% CI[a]	(1.06, 6.68)	(0.00, 1.61)
			Relative Risk (95% CI)[a]	7.08 (0.88, 56.95)	
			P-value	0.0659	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	4 (2.3)	2 (1.1)
			95% CI[a]	(0.07, 4.58)	(0.00, 2.73)
			Relative Risk (95% CI)[a]	2.02 (0.38, 10.90)	
			P-value	0.4122	
			Test for interaction[b]	0.3039	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	4 (3.3)	1 (0.8)
			95% CI[a]	(0.12, 6.44)	(0.00, 2.22)
			Relative Risk (95% CI)[a]	4.36 (0.49, 38.48)	
			P-value	0.1850	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	5 (3.8)	2 (1.7)
			95% CI[a]	(0.53, 7.04)	(0.00, 3.92)
			Relative Risk (95% CI)[a]	2.29 (0.45, 11.59)	
			P-value	0.3161	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	2 (1.9)	0
			95% CI[a]	(0.00, 4.39)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	4.13 (0.19, 90.54)	
			P-value	0.3680	
			Test for interaction[b]	0.8770	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_2

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	5 (2.9)	2 (1.1)
			95% CI[a]	(0.40, 5.42)	(0.00, 2.70)
			Relative Risk (95% CI)[a]	2.56 (0.50, 13.01)	
			P-value	0.2576	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	6 (3.2)	1 (0.5)
			95% CI[a]	(0.68, 5.70)	(0.00, 1.56)
			Relative Risk (95% CI)[a]	6.03 (0.73, 49.62)	
			P-value	0.0946	
			Test for interaction[b]	0.6669	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.3 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	7 (8.4)	0
			95% CI[a]	(2.46, 14.41)	(0.00, 3.45)
			Relative Risk (95% CI)[a]	17.80 (1.02, 309.07)	
			P-value	0.0481	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	4 (1.5)	3 (1.2)
			95% CI[a]	(0.04, 2.88)	(0.00, 2.46)
			Relative Risk (95% CI)[a]	1.26 (0.28, 5.58)	
			P-value	0.7604	
			Test for interaction[b]	0.0234	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_2

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	4 (1.7)	25 (10.1)
			95% CI[a]	(0.05, 3.43)	(6.36, 13.88)
			Relative Risk (95% CI)[a]	0.17 (0.06, 0.49)	
			P-value	0.0009	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	6 (4.5)	14 (11.9)
			95% CI[a]	(0.99, 8.10)	(6.03, 17.70)
			Relative Risk (95% CI)[a]	0.38 (0.15, 0.96)	
			P-value	0.0417	
			Test for interaction[b]	0.8350	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	10 (2.9)	39 (11.0)
			95% CI[a]	(1.14, 4.72)	(7.76, 14.28)
			Relative Risk (95% CI)[a]	0.27 (0.14, 0.52)	
			P-value	0.0001	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	0	0
			Test for interaction[b]	NE	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	9 (4.7)	22 (10.8)
			95% CI[a]	(1.69, 7.64)	(6.53, 15.04)
			Relative Risk (95% CI)[a]	0.43 (0.20, 0.92)	
			P-value	0.0285	
Sex: Female	Overall	Overall	N	169	161
			n (%)	1 (0.6)	17 (10.6)
			95% CI[a]	(0.00, 1.75)	(5.81, 15.31)
			Relative Risk (95% CI)[a]	0.06 (0.01, 0.42)	
			P-value	0.0049	
			Test for interaction[b]	0.3281	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	7 (2.6)	33 (13.3)
			95% CI[a]	(0.70, 4.50)	(9.08, 17.53)
			Relative Risk (95% CI)[a]	0.20 (0.09, 0.43)	
			P-value	<.0001	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	0	0
Race: Asian	Overall	Overall	N	62	83
			n (%)	3 (4.8)	5 (6.0)
			95% CI[a]	(0.00, 10.18)	(0.91, 11.14)
			Relative Risk (95% CI)[a]	0.80 (0.20, 3.23)	
			P-value	0.7579	
Race: Other	Overall	Overall	N	6	8
			n (%)	0	1 (12.5)
			95% CI[a]	(0.00, 45.93)	(0.00, 35.42)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_3

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
			Relative Risk (95% CI)[a]	0.62 (0.02, 15.61)	
			P-value	0.7685	
			Test for interaction[b]	0.0408	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	4 (2.3)	22 (11.3)
			95% CI[a]	(0.07, 4.45)	(6.84, 15.72)
			Relative Risk (95% CI)[a]	0.20 (0.07, 0.57)	
			P-value	0.0026	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	4 (2.7)	16 (12.1)
			95% CI[a]	(0.09, 5.24)	(6.55, 17.69)
			Relative Risk (95% CI)[a]	0.22 (0.08, 0.64)	
			P-value	0.0056	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	2 (11.8)	1 (5.3)
			95% CI[a]	(0.00, 27.08)	(0.00, 15.30)
			Relative Risk (95% CI)[a]	2.24 (0.22, 22.51)	
			P-value	0.4948	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.1573	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	3 (1.4)	28 (12.7)
			95% CI[a]	(0.00, 2.95)	(8.32, 17.13)
			Relative Risk (95% CI)[a]	0.11 (0.03, 0.35)	
			P-value	0.0002	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	7 (4.8)	11 (7.6)
			95% CI[a]	(1.33, 8.26)	(3.28, 11.90)
			Relative Risk (95% CI)[a]	0.63 (0.25, 1.58)	
			P-value	0.3280	
			Test for interaction[b]	0.0225	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_3

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	3 (7.5)	5 (9.8)
			95% CI[a]	(0.00, 15.66)	(1.64, 17.97)
			Relative Risk (95% CI)[a]	0.76 (0.19, 3.01)	
			P-value	0.7016	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	7 (2.2)	34 (10.8)
			95% CI[a]	(0.58, 3.77)	(7.39, 14.26)
			Relative Risk (95% CI)[a]	0.20 (0.09, 0.45)	
			P-value	<.0001	
			Test for interaction[b]	0.3211	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_3

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	2 (1.5)	18 (13.2)
			95% CI[a]	(0.00, 3.60)	(7.54, 18.93)
			Relative Risk (95% CI)[a]	0.11 (0.03, 0.48)	
			P-value	0.0032	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	8 (4.1)	18 (9.8)
			95% CI[a]	(1.31, 6.85)	(5.49, 14.08)
			Relative Risk (95% CI)[a]	0.42 (0.19, 0.94)	
			P-value	0.0340	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	0	3 (6.7)
			95% CI[a]	(0.00, 10.28)	(0.00, 13.95)
			Relative Risk (95% CI)[a]	0.22 (0.01, 4.20)	
			P-value	0.3124	
			Test for interaction[b]	0.2836	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_3

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	4 (1.8)	13 (5.9)
			95% CI[a]	(0.05, 3.55)	(2.79, 9.02)
			Relative Risk (95% CI)[a]	0.30 (0.10, 0.92)	
			P-value	0.0352	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	6 (4.3)	26 (17.9)
			95% CI[a]	(0.93, 7.64)	(11.69, 24.17)
			Relative Risk (95% CI)[a]	0.24 (0.10, 0.56)	
			P-value	0.0011	
			Test for interaction[b]	0.0177	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	3 (1.7)	23 (12.6)
			95% CI[a]	(0.00, 3.52)	(7.77, 17.37)
			Relative Risk (95% CI)[a]	0.13 (0.04, 0.43)	
			P-value	0.0008	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	6 (3.5)	16 (9.2)
			95% CI[a]	(0.75, 6.23)	(4.90, 13.49)
			Relative Risk (95% CI)[a]	0.38 (0.15, 0.95)	
			P-value	0.0377	
			Test for interaction[b]	0.1658	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_3

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	3 (2.5)	12 (9.0)
			95% CI[a]	(0.00, 5.21)	(4.15, 13.89)
			Relative Risk (95% CI)[a]	0.27 (0.08, 0.94)	
			P-value	0.0401	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	4 (3.0)	17 (14.0)
			95% CI[a]	(0.11, 5.95)	(7.86, 20.24)
			Relative Risk (95% CI)[a]	0.22 (0.07, 0.62)	
			P-value	0.0046	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	3 (2.8)	10 (9.0)
			95% CI[a]	(0.00, 5.88)	(3.68, 14.34)
			Relative Risk (95% CI)[a]	0.31 (0.09, 1.09)	
			P-value	0.0678	
			Test for interaction[b]	0.5188	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_3

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	5 (2.9)	17 (9.7)
			95% CI[a]	(0.40, 5.42)	(5.29, 14.02)
			Relative Risk (95% CI)[a]	0.30 (0.11, 0.80)	
			P-value	0.0158	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	5 (2.7)	22 (11.6)
			95% CI[a]	(0.36, 4.96)	(7.07, 16.21)
			Relative Risk (95% CI)[a]	0.23 (0.09, 0.59)	
			P-value	0.0023	
			Test for interaction[b]	0.5396	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_3

Table 14.3.1.6.10.4 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set (Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	2 (2.4)	15 (14.3)
			95% CI[a]	(0.00, 5.71)	(7.59, 20.98)
			Relative Risk (95% CI)[a]	0.17 (0.04, 0.72)	
			P-value	0.0159	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	8 (2.9)	24 (9.3)
			95% CI[a]	(0.93, 4.91)	(5.74, 12.80)
			Relative Risk (95% CI)[a]	0.32 (0.14, 0.69)	
			P-value	0.0038	
			Test for interaction[b]	0.2035	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.11 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Table not created
No participant meets the reporting criteria

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_14

Table 14.3.1.6.12 Abrocitinib
Proportion of Subjects with Special Interest Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Table not created
No participant meets the reporting criteria

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_15

Proportion of Subjects with Serious Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Table not created
No participant meets the reporting criteria

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Severe Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Table not created
No participant meets the reporting criteria

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	5 (2.2)	8 (3.2)
			95% CI[a]	(0.29, 4.06)	(1.03, 5.45)
			Relative Risk (95% CI)[a]	0.67 (0.22, 2.02)	
			P-value	0.4786	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	4 (3.0)	1 (0.8)
			95% CI[a]	(0.11, 5.95)	(0.00, 2.50)
			Relative Risk (95% CI)[a]	3.58 (0.41, 31.54)	
			P-value	0.2514	
			Test for interaction[b]	0.1535	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_18

Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<65, >=65)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Age (years) group: <65	Overall	Overall	N	341	354
			n (%)	8 (2.3)	9 (2.5)
			95% CI[a]	(0.74, 3.95)	(0.90, 4.18)
			Relative Risk (95% CI)[a]	0.92 (0.36, 2.36)	
			P-value	0.8670	
Age (years) group: >=65	Overall	Overall	N	21	11
			n (%)	1 (4.8)	0
			95% CI[a]	(0.00, 13.87)	(0.00, 28.49)
			Relative Risk (95% CI)[a]	1.10 (0.04, 30.23)	
			P-value	0.9571	
			Test for interaction[b]	0.9371	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Sex: Male	Overall	Overall	N	193	204
			n (%)	2 (1.0)	4 (2.0)
			95% CI[a]	(0.00, 2.46)	(0.06, 3.86)
			Relative Risk (95% CI)[a]	0.53 (0.10, 2.85)	
			P-value	0.4585	
Sex: Female	Overall	Overall	N	169	161
			n (%)	7 (4.1)	5 (3.1)
			95% CI[a]	(1.14, 7.15)	(0.43, 5.79)
			Relative Risk (95% CI)[a]	1.33 (0.43, 4.12)	
			P-value	0.6165	
			Test for interaction[b]	0.4137	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: White	Overall	Overall	N	269	248
			n (%)	6 (2.2)	7 (2.8)
			95% CI[a]	(0.47, 4.00)	(0.76, 4.88)
			Relative Risk (95% CI)[a]	0.79 (0.27, 2.32)	
			P-value	0.6682	
Race: Black Or African American	Overall	Overall	N	25	26
			n (%)	1 (4.0)	0
			95% CI[a]	(0.00, 11.68)	(0.00, 13.23)
			Relative Risk (95% CI)[a]	2.12 (0.07, 60.46)	
			P-value	0.6603	
Race: Asian	Overall	Overall	N	62	83
			n (%)	2 (3.2)	2 (2.4)
			95% CI[a]	(0.00, 7.62)	(0.00, 5.71)
			Relative Risk (95% CI)[a]	1.34 (0.19, 9.24)	
			P-value	0.7673	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Race

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Race: Other	Overall	Overall	N	6	8
			n (%)	0	0
			Test for interaction[b]	0.9256	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	5 (2.8)	3 (1.5)
			95% CI[a]	(0.38, 5.27)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	1.84 (0.45, 7.57)	
			P-value	0.4006	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	3 (2.0)	6 (4.5)
			95% CI[a]	(0.00, 4.24)	(0.99, 8.10)
			Relative Risk (95% CI)[a]	0.44 (0.11, 1.72)	
			P-value	0.2388	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	1 (5.9)	0
			95% CI[a]	(0.00, 17.07)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.29 (0.08, 64.21)	
			P-value	0.6252	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.5066	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	7 (3.2)	5 (2.3)
			95% CI[a]	(0.88, 5.60)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	1.43 (0.46, 4.42)	
			P-value	0.5391	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	2 (1.4)	4 (2.8)
			95% CI[a]	(0.00, 3.26)	(0.09, 5.42)
			Relative Risk (95% CI)[a]	0.50 (0.09, 2.67)	
			P-value	0.4146	
			Test for interaction[b]	0.3041	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Previous cyclosporine exposure

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Previous cyclosporine exposure: Cyclosporine Exposed	Overall	Overall	N	40	51
			n (%)	1 (2.5)	1 (2.0)
			95% CI[a]	(0.00, 7.34)	(0.00, 5.77)
			Relative Risk (95% CI)[a]	1.27 (0.08, 19.76)	
			P-value	0.8621	
Previous cyclosporine exposure: Cyclosporine Naive	Overall	Overall	N	322	314
			n (%)	8 (2.5)	8 (2.5)
			95% CI[a]	(0.78, 4.18)	(0.80, 4.29)
			Relative Risk (95% CI)[a]	0.98 (0.37, 2.57)	
			P-value	0.9594	
			Test for interaction[b]	0.8585	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Weight

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Weight(kg): <70	Overall	Overall	N	132	136
			n (%)	5 (3.8)	4 (2.9)
			95% CI[a]	(0.53, 7.04)	(0.10, 5.78)
			Relative Risk (95% CI)[a]	1.29 (0.35, 4.69)	
			P-value	0.7013	
Weight(kg): >=70 and <=100	Overall	Overall	N	196	184
			n (%)	3 (1.5)	4 (2.2)
			95% CI[a]	(0.00, 3.25)	(0.07, 4.28)
			Relative Risk (95% CI)[a]	0.70 (0.16, 3.10)	
			P-value	0.6429	
Weight(kg): >100	Overall	Overall	N	34	45
			n (%)	1 (2.9)	1 (2.2)
			95% CI[a]	(0.00, 8.62)	(0.00, 6.53)
			Relative Risk (95% CI)[a]	1.32 (0.09, 20.41)	
			P-value	0.8408	
			Test for interaction[b]	0.8244	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

AD Duration

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
AD Duration (years) group: <26	Overall	Overall	N	222	220
			n (%)	6 (2.7)	4 (1.8)
			95% CI[a]	(0.57, 4.84)	(0.05, 3.58)
			Relative Risk (95% CI)[a]	1.49 (0.43, 5.20)	
			P-value	0.5347	
AD Duration (years) group: >=26	Overall	Overall	N	140	145
			n (%)	3 (2.1)	5 (3.4)
			95% CI[a]	(0.00, 4.54)	(0.48, 6.42)
			Relative Risk (95% CI)[a]	0.62 (0.15, 2.55)	
			P-value	0.5091	
			Test for interaction[b]	0.3635	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_18

Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline EASI group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline EASI group: 16-25	Overall	Overall	N	181	183
			n (%)	6 (3.3)	4 (2.2)
			95% CI[a]	(0.71, 5.92)	(0.07, 4.30)
			Relative Risk (95% CI)[a]	1.52 (0.44, 5.28)	
			P-value	0.5132	
Baseline EASI group: >25	Overall	Overall	N	172	174
			n (%)	3 (1.7)	5 (2.9)
			95% CI[a]	(0.00, 3.70)	(0.39, 5.36)
			Relative Risk (95% CI)[a]	0.61 (0.15, 2.50)	
			P-value	0.4895	
			Test for interaction[b]	0.3380	
Baseline EASI group: Missing	Overall	Overall	N	9	8

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline % BSA group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline %BSA group: 10-30	Overall	Overall	N	122	133
			n (%)	2 (1.6)	2 (1.5)
			95% CI[a]	(0.00, 3.89)	(0.00, 3.57)
			Relative Risk (95% CI)[a]	1.09 (0.16, 7.62)	
			P-value	0.9307	
Baseline %BSA group: >30-50	Overall	Overall	N	132	121
			n (%)	5 (3.8)	3 (2.5)
			95% CI[a]	(0.53, 7.04)	(0.00, 5.25)
			Relative Risk (95% CI)[a]	1.53 (0.37, 6.26)	
			P-value	0.5558	
Baseline %BSA group: >50	Overall	Overall	N	108	111
			n (%)	2 (1.9)	4 (3.6)
			95% CI[a]	(0.00, 4.39)	(0.14, 7.07)
			Relative Risk (95% CI)[a]	0.51 (0.10, 2.75)	
			P-value	0.4364	
			Test for interaction[b]	0.6067	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
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Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Prior AD medications

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Prior AD medications: Systemic Agents	Overall	Overall	N	172	176
			n (%)	2 (1.2)	3 (1.7)
			95% CI[a]	(0.00, 2.76)	(0.00, 3.62)
			Relative Risk (95% CI)[a]	0.68 (0.12, 4.03)	
			P-value	0.6731	
Prior AD medications: Topical Agents Only	Overall	Overall	N	188	189
			n (%)	7 (3.7)	6 (3.2)
			95% CI[a]	(1.02, 6.43)	(0.68, 5.67)
			Relative Risk (95% CI)[a]	1.17 (0.40, 3.42)	
			P-value	0.7706	
			Test for interaction[b]	0.6323	
Prior AD medications: Missing	Overall	Overall	N	2	0

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_18

Table 14.3.1.6.15 Abrocitinib
Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline PP-NRS group

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	**System Organ Class**	**MedDRA Preferred Term**		**n (%)**	**n (%)**
Baseline PP-NRS group: 4-6	Overall	Overall	N	83	105
			n (%)	4 (4.8)	5 (4.8)
			95% CI[a]	(0.21, 9.43)	(0.69, 8.84)
			Relative Risk (95% CI)[a]	1.01 (0.28, 3.65)	
			P-value	0.9854	
Baseline PP-NRS group: >=7	Overall	Overall	N	274	259
			n (%)	5 (1.8)	4 (1.5)
			95% CI[a]	(0.24, 3.41)	(0.04, 3.05)
			Relative Risk (95% CI)[a]	1.18 (0.32, 4.35)	
			P-value	0.8020	
			Test for interaction[b]	0.9485	
Baseline PP-NRS group: Missing	Overall	Overall	N	5	1

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

TABLE 5.4.1: Non-Severe Treatment Emergent Subset Flag Adverse Events, overall and by SOC/PT - Safety Population

System Organ Class (SOC) Preferred Term (PT)	Abrocitinib 200mg QD N=362	Dupilumab 300mg Q2W N=365	Total Population N=727
Overall	195 (53.9%)	129 (35.3%)	324 (44.6%)
Infections and infestations	67 (18.5%)	76 (20.8%)	143 (19.7%)
Conjunctivitis	8 (2.2%)	35 (9.6%)	43 (5.9%)
COVID-19	14 (3.9%)	12 (3.3%)	26 (3.6%)
Nasopharyngitis	14 (3.9%)	12 (3.3%)	26 (3.6%)
Oral herpes	9 (2.5%)	15 (4.1%)	24 (3.3%)
Upper respiratory tract infection	10 (2.8%)	9 (2.5%)	19 (2.6%)
Herpes simplex	12 (3.3%)	5 (1.4%)	17 (2.3%)
Folliculitis	12 (3.3%)	3 (0.8%)	15 (2.1%)
Skin and subcutaneous tissue disorders	60 (16.6%)	23 (6.3%)	83 (11.4%)
Acne	46 (12.7%)	10 (2.7%)	56 (7.7%)
Dermatitis atopic	16 (4.4%)	14 (3.8%)	30 (4.1%)
Gastrointestinal disorders	70 (19.3%)	11 (3.0%)	81 (11.1%)
Nausea	70 (19.3%)	8 (2.2%)	78 (10.7%)
Vomiting	11 (3.0%)	6 (1.6%)	17 (2.3%)
Nervous system disorders	54 (14.9%)	27 (7.4%)	81 (11.1%)
Headache	46 (12.7%)	24 (6.6%)	70 (9.6%)
Dizziness	10 (2.8%)	4 (1.1%)	14 (1.9%)
Investigations	38 (10.5%)	26 (7.1%)	64 (8.8%)
SARS-CoV-2 test positive	15 (4.1%)	13 (3.6%)	28 (3.9%)
Blood creatine phosphokinase increased	14 (3.9%)	13 (3.6%)	27 (3.7%)
Natural killer cell count decreased	10 (2.8%)	0	10 (1.4%)
General disorders and administration site conditions	10 (2.8%)	5 (1.4%)	15 (2.1%)
Fatigue	10 (2.8%)	5 (1.4%)	15 (2.1%)

Note(s):
Safety Population
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.05 Safety Incidences SOCPT.sas] run Thursday, November 11, 2021 at 11:26:34

TABLE 4.1: Binary Outcome Analysis: Medicated Topical Background Therapy-Free days Defined by SCORAD-90 - Full Analysis Set Population

Analysis / Population	Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Overall		
Observed Values		
N subjects	362	365
Mean (SD)	15.2 (34.6)	6.2 (21.5)
p25, median, p75, p90, p95	0, 0, 0, 71, 102	0, 0, 0, 22, 49
Min, Max	0, 154	0, 183
ANCOVA Least-square means model		
LSM Estimates (SE)	15.2 (1.5)	6.2 (1.5)
(95% CI)	(12.2, 18.2)	(3.3, 9.2)
Treatment Difference Estimate (SE)		8.9 (2.1)
(95% CI)		(4.8, 13.1)
p-value		<.0001

Notes:
Least-Square Means results are based on an ANCOVA model with treatment and stratum (disease activity (moderate, severe) at enrollment) as independent variables, and the number of response days as dependent variable.
Number of subjects: Full Analysis Set Population
ANCOVA: Analysis of Covariance; CI: Confidence Interval; LSM: Least Square Means; SD: Standard Deviation; SE: Standard Error.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.04 ANCOVA-DaysWithResponse.sas] run Thursday, November 11, 2021 at 10:04:21

TABLE 4.2: Binary Outcome Analysis: Medicated Topical Background Therapy-Free days Defined by EASI-90 - Full Analysis Set Population

Analysis / Population	Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Overall		
Observed Values		
N subjects	362	365
Mean (SD)	51.4 (56.6)	33.3 (47.5)
p25, median, p75, p90, p95	0, 32, 96, 146, 155	0, 0, 67, 107, 129
Min, Max	0, 170	0, 183
ANCOVA Least-square means model		
LSM Estimates (SE)	51.4 (2.7)	33.3 (2.7)
(95% CI)	(46.0, 56.8)	(27.9, 38.7)
Treatment Difference Estimate (SE)		18.1 (3.9)
(95% CI)		(10.5, 25.7)
p-value		<.0001

Notes:
Least-Square Means results are based on an ANCOVA model with treatment and stratum (disease activity (moderate, severe) at enrollment) as independent variables, and the number of response days as dependent variable.
Number of subjects: Full Analysis Set Population
ANCOVA: Analysis of Covariance; CI: Confidence Interval; LSM: Least Square Means; SD: Standard Deviation; SE: Standard Error.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.04 ANCOVA-DaysWithResponse.sas] run Thursday, November 11, 2021 at 10:04:26

TABLE 4.3: Binary Outcome Analysis: Medicated Topical Background Therapy-Free days Defined by POEM 0-2 - Full Analysis Set Population

Analysis / Population	Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Overall		
Observed Values		
N subjects	358	363
Mean (SD)	19.3 (36.8)	7.7 (24.4)
p25, median, p75, p90, p95	0, 0, 0, 99, 100	0, 0, 0, 22, 78
Min, Max	0, 113	0, 101
ANCOVA Least-square means model		
LSM Estimates (SE)	19.3 (1.6)	7.7 (1.6)
(95% CI)	(16.0, 22.5)	(4.5, 10.9)
Treatment Difference Estimate (SE)		11.6 (2.3)
(95% CI)		(7.0, 16.1)
p-value		<.0001

Notes:
Least-Square Means results are based on an ANCOVA model with treatment and stratum (disease activity (moderate, severe) at enrollment) as independent variables, and the number of response days as dependent variable.
Number of subjects: Full Analysis Set Population, excluding subjects with baseline POEM 0-2.
ANCOVA: Analysis of Covariance; CI: Confidence Interval; LSM: Least Square Means; SD: Standard Deviation; SE: Standard Error.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.04 ANCOVA-DaysWithResponse.sas] run Thursday, November 11, 2021 at 10:04:31

TABLE 4.4: Binary Outcome Analysis: Medicated Topical Background Therapy-Free days Defined by DLQI 0-1 - Full Analysis Set Population

Analysis / Population	Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Overall		
Observed Values		
N subjects	359	363
Mean (SD)	35.8 (51.2)	22.4 (39.5)
p25, median, p75, p90, p95	0, 0, 72, 104, 167	0, 0, 39, 99, 100
Min, Max	0, 185	0, 189
ANCOVA Least-square means model		
LSM Estimates (SE)	35.8 (2.4)	22.4 (2.4)
(95% CI)	(31.0, 40.5)	(17.7, 27.1)
Treatment Difference Estimate (SE)		13.4 (3.4)
(95% CI)		(6.7, 20.0)
p-value		<.0001

Notes:
Least-Square Means results are based on an ANCOVA model with treatment and stratum (disease activity (moderate, severe) at enrollment) as independent variables, and the number of response days as dependent variable.
Number of subjects: Full Analysis Set Population, excluding subjects with baseline DLQI 0-1.
ANCOVA: Analysis of Covariance; CI: Confidence Interval; LSM: Least Square Means; SD: Standard Deviation; SE: Standard Error.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.04 ANCOVA-DaysWithResponse.sas] run Thursday, November 11, 2021 at 10:04:35

TABLE 4.5: Binary Outcome Analysis: Response days Defined by SCORAD-90 - Full Analysis Set Population

Analysis / Population	Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Overall		
Observed Values		
N subjects	362	365
Mean (SD)	17.6 (37.9)	7.1 (23.6)
p25, median, p75, p90, p95	0, 0, 0, 85, 112	0, 0, 0, 29, 67
Min, Max	0, 156	0, 183
ANCOVA Least-square means model		
LSM Estimates (SE)	17.7 (1.7)	7.1 (1.7)
(95% CI)	(14.4, 20.9)	(3.8, 10.3)
Treatment Difference Estimate (SE)		10.6 (2.3)
(95% CI)		(6.0, 15.2)
p-value		<.0001

Notes:
Least-Square Means results are based on an ANCOVA model with treatment and stratum (disease activity (moderate, severe) at enrollment) as independent variables, and the number of response days as dependent variable.
Number of subjects: Full Analysis Set Population
ANCOVA: Analysis of Covariance; CI: Confidence Interval; LSM: Least Square Means; SD: Standard Deviation; SE: Standard Error.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.04 ANCOVA-DaysWithResponse.sas] run Thursday, November 11, 2021 at 10:04:40

TABLE 4.6: Binary Outcome Analysis: Response days Defined by EASI-90 - Full Analysis Set Population

Analysis / Population	Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Overall		
Observed Values		
N subjects	362	365
Mean (SD)	62.1 (62.5)	42.2 (55.7)
p25, median, p75, p90, p95	0, 47, 126, 155, 161	0, 0, 88, 129, 156
Min, Max	0, 204	0, 183
ANCOVA Least-square means model		
LSM Estimates (SE)	62.1 (3.1)	42.1 (3.1)
(95% CI)	(56.0, 68.2)	(36.1, 48.2)
Treatment Difference Estimate (SE)		19.9 (4.4)
(95% CI)		(11.3, 28.6)
p-value		<.0001

Notes:
Least-Square Means results are based on an ANCOVA model with treatment and stratum (disease activity (moderate, severe) at enrollment) as independent variables, and the number of response days as dependent variable.
Number of subjects: Full Analysis Set Population
ANCOVA: Analysis of Covariance; CI: Confidence Interval; LSM: Least Square Means; SD: Standard Deviation; SE: Standard Error.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.04 ANCOVA-DaysWithResponse.sas] run Thursday, November 11, 2021 at 10:04:45

TABLE 4.7: Binary Outcome Analysis: Response days Defined by POEM 0-2 - Full Analysis Set Population

Analysis / Population	Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Overall		
Observed Values		
N subjects	358	363
Mean (SD)	20.9 (38.7)	9.4 (27.3)
p25, median, p75, p90, p95	0, 0, 0, 99, 100	0, 0, 0, 32, 98
Min, Max	0, 113	0, 101
ANCOVA Least-square means model		
LSM Estimates (SE)	20.9 (1.8)	9.4 (1.8)
(95% CI)	(17.4, 24.3)	(6.0, 12.9)
Treatment Difference Estimate (SE)		11.5 (2.5)
(95% CI)		(6.6, 16.4)
p-value		<.0001

Notes:
Least-Square Means results are based on an ANCOVA model with treatment and stratum (disease activity (moderate, severe) at enrollment) as independent variables, and the number of response days as dependent variable.
Number of subjects: Full Analysis Set Population, excluding subjects with baseline POEM 0-2.
ANCOVA: Analysis of Covariance; CI: Confidence Interval; LSM: Least Square Means; SD: Standard Deviation; SE: Standard Error.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.04 ANCOVA-DaysWithResponse.sas] run Thursday, November 11, 2021 at 10:04:49

TABLE 4.8: Binary Outcome Analysis: Response days Defined by DLQI 0-1 - Full Analysis Set Population

Analysis / Population	Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Overall		
Observed Values		
N subjects	359	363
Mean (SD)	42.3 (58.5)	26.9 (45.3)
p25, median, p75, p90, p95	0, 0, 97, 168, 170	0, 0, 44, 99, 103
Min, Max	0, 185	0, 197
ANCOVA Least-square means model		
LSM Estimates (SE)	42.3 (2.8)	26.9 (2.7)
(95% CI)	(36.9, 47.7)	(21.5, 32.3)
Treatment Difference Estimate (SE)		15.4 (3.9)
(95% CI)		(7.7, 23.0)
p-value		<.0001

Notes:
Least-Square Means results are based on an ANCOVA model with treatment and stratum (disease activity (moderate, severe) at enrollment) as independent variables, and the number of response days as dependent variable.
Number of subjects: Full Analysis Set Population, excluding subjects with baseline DLQI 0-1.
ANCOVA: Analysis of Covariance; CI: Confidence Interval; LSM: Least Square Means; SD: Standard Deviation; SE: Standard Error.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.04 ANCOVA-DaysWithResponse.sas] run Thursday, November 11, 2021 at 10:04:51

TABLE 3.1: Binary Outcome Analysis: SCORAD-90 response by visit - Full Analysis Set Population

Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD			
n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH p-value [+]
Overall							
-Visit Week 2							
362	7 (1.9%) (0.8%, 3.9%)	365	2 (0.5%) (0.1%, 2.0%)	3.65 (0.75, 17.78)	3.56 (0.75, 16.97)	1.4% (-0.2%, 3.0%)	0.0873+
-Visit Week 4							
362	28 (7.7%) (5.2%, 11.0%)	365	7 (1.9%) (0.8%, 3.9%)	4.29 (1.85, 9.97)	4.04 (1.79, 9.16)	5.8% (2.7%, 8.9%)	0.0003+*
-Visit Week 8							
362	48 (13.3%) (9.9%, 17.2%)	365	15 (4.1%) (2.3%, 6.7%)	3.58 (1.96, 6.53)	3.23 (1.84, 5.67)	9.2% (5.1%, 13.2%)	<0.0001+*
-Visit Week 12							
362	60 (16.6%) (12.9%, 20.8%)	365	24 (6.6%) (4.3%, 9.6%)	2.82 (1.71, 4.64)	2.52 (1.61, 3.96)	10.0% (5.4%, 14.6%)	<0.0001+*
-Visit Week 16							
362	71 (19.6%) (15.6%, 24.1%)	365	31 (8.5%) (5.8%, 11.8%)	2.62 (1.67, 4.10)	2.31 (1.55, 3.43)	11.1% (6.1%, 16.1%)	<0.0001+*
-Visit Week 20							
362	79 (21.8%) (17.7%, 26.4%)	365	44 (12.1%) (8.9%, 15.8%)	2.03 (1.36, 3.04)	1.81 (1.29, 2.54)	9.8% (4.4%, 15.2%)	0.0004+*
-Visit Week 26							
362	80 (22.1%) (17.9%, 26.7%)	365	52 (14.2%) (10.8%, 18.3%)	1.71 (1.16, 2.51)	1.55 (1.13, 2.13)	7.9% (2.3%, 13.4%)	0.0061+*

Notes:
Number of subjects: Full Analysis Set Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.03 Binary Efficacy.sas] run Monday, November 22, 2021 at 13:00:28

TABLE 3.2: Binary Outcome Analysis: EASI-90 response by visit - Full Analysis Set Population

Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD			
n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH p-value [+]
Overall							
-Visit Week 2							
362	42 (11.6%) (8.5%, 15.4%)	365	26 (7.1%) (4.7%, 10.3%)	1.72 (1.03, 2.88)	1.63 (1.02, 2.60)	4.5% (0.3%, 8.7%)	0.0368+*
-Visit Week 4							
362	101 (27.9%) (23.3%, 32.8%)	365	53 (14.5%) (11.1%, 18.6%)	2.29 (1.58, 3.32)	1.93 (1.43, 2.60)	13.4% (7.6%, 19.3%)	<0.0001+*
-Visit Week 8							
362	161 (44.5%) (39.3%, 49.8%)	365	92 (25.2%) (20.8%, 30.0%)	2.38 (1.74, 3.27)	1.77 (1.43, 2.18)	19.3% (12.5%, 26.1%)	<0.0001+*
-Visit Week 12							
362	171 (47.2%) (42.0%, 52.5%)	365	122 (33.4%) (28.6%, 38.5%)	1.79 (1.32, 2.41)	1.41 (1.18, 1.69)	13.8% (6.8%, 20.9%)	0.0001+*
-Visit Week 16							
362	194 (53.6%) (48.3%, 58.8%)	365	151 (41.4%) (36.3%, 46.6%)	1.64 (1.22, 2.20)	1.30 (1.11, 1.51)	12.3% (5.1%, 19.5%)	0.0009+*
-Visit Week 20							
362	208 (57.5%) (52.2%, 62.6%)	365	166 (45.5%) (40.3%, 50.7%)	1.62 (1.21, 2.17)	1.26 (1.10, 1.46)	12.0% (4.8%, 19.2%)	0.0012+*
-Visit Week 26							
362	190 (52.5%) (47.2%, 57.7%)	365	172 (47.1%) (41.9%, 52.4%)	1.24 (0.93, 1.66)	1.11 (0.96, 1.29)	5.4% (-1.9%, 12.6%)	0.1470+

Notes:
Number of subjects: Full Analysis Set Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.03 Binary Efficacy.sas] run Monday, November 22, 2021 at 13:00:40

TABLE 3.3: Binary Outcome Analysis: Achieving 0-2 in POEM total score by visit - Full Analysis Set Population

Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD			
n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH p-value [+]
Overall							
-Visit Week 12							
358	108 (30.2%) (25.5%, 35.2%)	363	61 (16.8%) (13.1%, 21.1%)	2.14 (1.50, 3.05)	1.79 (1.36, 2.37)	13.4% (7.2%, 19.5%)	<0.0001+*
-Visit Week 16							
358	104 (29.1%) (24.4%, 34.1%)	363	55 (15.2%) (11.6%, 19.3%)	2.29 (1.59, 3.31)	1.92 (1.43, 2.57)	13.9% (7.9%, 19.9%)	<0.0001+*
-Visit Week 26							
358	106 (29.6%) (24.9%, 34.6%)	363	69 (19.0%) (15.1%, 23.4%)	1.79 (1.27, 2.54)	1.56 (1.19, 2.03)	10.6% (4.4%, 16.8%)	0.0009+*

Notes:
Number of subjects: Full Analysis Set Population
Number of subjects: Full Analysis Set Population, excluding subjects with baseline POEM 0-2.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.03 Binary Efficacy.sas] run Monday, November 22, 2021 at 13:00:48

TABLE 3.4: Binary Outcome Analysis: Achieving 0-1 in DLQI total score by visit - Full Analysis Set Population

Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD			
n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH p-value [+]
Overall							
-Visit Week 2							
358	81 (22.6%) (18.4%, 27.3%)	361	23 (6.4%) (4.1%, 9.4%)	4.31 (2.64, 7.03)	3.56 (2.29, 5.52)	16.3% (11.3%, 21.3%)	<0.0001+*
-Visit Week 12							
358	126 (35.2%) (30.2%, 40.4%)	361	110 (30.5%) (25.8%, 35.5%)	1.24 (0.91, 1.69)	1.16 (0.94, 1.43)	4.7% (-2.1%, 11.6%)	0.1758+
-Visit Week 16							
358	147 (41.1%) (35.9%, 46.4%)	361	107 (29.6%) (25.0%, 34.6%)	1.65 (1.21, 2.25)	1.39 (1.13, 1.69)	11.4% (4.5%, 18.4%)	0.0014+*
-Visit Week 20							
358	154 (43.0%) (37.8%, 48.3%)	361	119 (33.0%) (28.1%, 38.1%)	1.53 (1.13, 2.08)	1.30 (1.08, 1.58)	10.0% (3.0%, 17.1%)	0.0056+*
-Visit Week 26							
358	137 (38.3%) (33.2%, 43.5%)	361	114 (31.6%) (26.8%, 36.6%)	1.34 (0.99, 1.83)	1.21 (0.99, 1.48)	6.7% (-0.2%, 13.7%)	0.0596+

Notes:
Number of subjects: Full Analysis Set Population
Number of subjects: Full Analysis Set Population, excluding subjects with baseline DLQI 0-1.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.
Analysis Cut Off date: 06AUG2021
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TABLE 3.5: Binary Outcome Analysis: Objective SCORAD-90 response at week 26 - Full Analysis Set Population

Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD			
n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH p-value [+]
Overall							
-Visit Week 26							
362	82 (22.7%) (18.4%, 27.3%)	365	53 (14.5%) (11.1%, 18.6%)	1.72 (1.18, 2.52)	1.56 (1.14, 2.13)	8.1% (2.5%, 13.8%)	0.0048+*

Notes:
Number of subjects: Full Analysis Set Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.03 Binary Efficacy.sas] run Monday, November 22, 2021 at 13:01:05