Clinical trial results:
A Phase 3b Randomized, Double-Blind, Double-Dummy, Active Controlled Multi-Center Study Assessing The Efficacy And Safety Of Abrocitinib Compared With Dupilumab In Adult Participants On Background Topical Therapy With Moderate To Severe Atopic Dermatitis

Summary

EudraCT number	2019-004013-13
Trial protocol	GB LV SK BE HU CZ DK FI BG FR IT
Global end of trial date	13 July 2021

Results information

Result version number	v1 (current)
This version publication date	24 June 2022
First version publication date	24 June 2022

Trial information

Trial identification

Sponsor protocol code	B7451050

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, NY 10017, United States,
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	09 December 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 July 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy of abrocitinib 200 mg once daily (QD) versus dupilumab 300 mg once every 2 weeks (Q2W) (as per label guidelines) in adult subjects on background topical therapy with moderate to severe atopic dermatitis (AD).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 June 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 51
Country: Number of subjects enrolled	Bulgaria: 17
Country: Number of subjects enrolled	Canada: 196
Country: Number of subjects enrolled	Chile: 37
Country: Number of subjects enrolled	Finland: 10
Country: Number of subjects enrolled	Germany: 66
Country: Number of subjects enrolled	Hungary: 21
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Korea, Republic of: 25
Country: Number of subjects enrolled	Latvia: 7
Country: Number of subjects enrolled	Poland: 135
Country: Number of subjects enrolled	Slovakia: 16
Country: Number of subjects enrolled	Spain: 9
Country: Number of subjects enrolled	Taiwan: 11
Country: Number of subjects enrolled	United States: 125
Worldwide total number of subjects	727
EEA total number of subjects	282

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	695
From 65 to 84 years	32
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was a double-blind, double-dummy, active-controlled study in adult subjects with moderate to severe atopic dermatitis. The study was conducted across 143 sites in 15 countries.

Pre-assignment

Screening details:

A total of 940 subjects were screened, of which 213 were screen failures and were not enrolled. 727 subjects were enrolled in the study and assigned to a study intervention.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Abrocitinib 200 mg QD

Arm description:

Subjects were administered abrocitinib 200 mg (2 x 100 mg) oral tablets once daily (QD) from Day 1 to Week 26 along with dupilumab-matching placebo administered as a subcutaneous injection once every 2 weeks (Q2W) until Week 24. Subjects were followed for up to 4 weeks post last dose of study intervention.

Arm type	Experimental
Investigational medicinal product name	Dupilumab Matching Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Dupilumab-matching placebo was administered as a subcutaneous injection once every 2 weeks until Week 24.

Investigational medicinal product name	Abrocitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Abrocitinib was available as 100 mg tablets to be administered at a dose of 200 mg once daily orally from Day 1 to Week 26.

Arm title	Dupilumab 300 mg Q2W

Arm description:

Subjects were administered dupilumab 300 mg as a subcutaneous injection Q2W until Week 24 along with abrocitinib-matching placebo oral tablets administered once daily from Day 1 to Week 26. Subjects were followed for up to 4 weeks post last dose of study intervention.

Arm type	Active comparator

Investigational medicinal product name	Abrocitinib Matching Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Abrocitinib-matching placebo tablets were administered once daily orally from Day 1 to Week 26.

Investigational medicinal product name	Dupilumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Dupilumab was administered at a dose of 300 mg as a subcutaneous injection Q2W until Week 24.

Number of subjects in period 1	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W
Started	362	365
Completed	327	334
Not completed	35	31
Consent withdrawn by subject	11	11
Adverse event, non-fatal	10	9
Death	2	-
Unspecified	3	4
Medication Error Without Associated Adverse Event	1	-
Lost to follow-up	2	4
Protocol deviation	4	3
Lack of efficacy	2	-

Baseline characteristics

Reporting groups	
Reporting group title	Abrocitinib 200 mg QD
Reporting group description:	
Subjects were administered abrocitinib 200 mg (2 x 100 mg) oral tablets once daily (QD) from Day 1 to Week 26 along with dupilumab-matching placebo administered as a subcutaneous injection once every 2 weeks (Q2W) until Week 24. Subjects were followed for up to 4 weeks post last dose of study intervention.	
Reporting group title	Dupilumab 300 mg Q2W
Reporting group description:	
Subjects were administered dupilumab 300 mg as a subcutaneous injection Q2W until Week 24 along with abrocitinib-matching placebo oral tablets administered once daily from Day 1 to Week 26. Subjects were followed for up to 4 weeks post last dose of study intervention.	

Reporting group values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W	Total
Number of subjects	362	365	727
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	341	354	695
From 65-84 years	21	11	32
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	36.6	35.5	
standard deviation	± 14.6	± 13.3	-
Sex: Female, Male Units: Subjects			
Female	169	161	330
Male	193	204	397
Race Units: Subjects			
American Indian or Alaska Native	1	0	1
Asian	62	83	145
Native Hawaiian or Other Pacific Islander	1	0	1
Black or African American	25	26	51
White	269	248	517
More than one race	0	3	3
Unknown or Not Reported	4	5	9
Ethnicity Units: Subjects			
Hispanic or Latino	30	27	57

Not Hispanic or Latino	331	337	668
Unknown or Not Reported	1	1	2

End points

End points reporting groups

Reporting group title	Abrocitinib 200 mg QD

Reporting group description:

Subjects were administered abrocitinib 200 mg (2 x 100 mg) oral tablets once daily (QD) from Day 1 to Week 26 along with dupilumab-matching placebo administered as a subcutaneous injection once every 2 weeks (Q2W) until Week 24. Subjects were followed for up to 4 weeks post last dose of study intervention.

Reporting group title	Dupilumab 300 mg Q2W

Reporting group description:

Subjects were administered dupilumab 300 mg as a subcutaneous injection Q2W until Week 24 along with abrocitinib-matching placebo oral tablets administered once daily from Day 1 to Week 26. Subjects were followed for up to 4 weeks post last dose of study intervention.

Primary: Percentage of Subjects Achieving Greater Than or Equal to (>=) 4 Points Improvement in Peak Pruritus Numerical Rating Scale (PP-NRS4) from Baseline at Week 2

End point title	Percentage of Subjects Achieving Greater Than or Equal to (>=) 4 Points Improvement in Peak Pruritus Numerical Rating Scale (PP-NRS4) from Baseline at Week 2

End point description:

The severity of itch (pruritus) due to AD was assessed using the PP-NRS, a validated horizontal NRS. Subjects were asked to assess their worst itching due to AD over the past 24 hours on an NRS with scale ranging from 0 to 10, where 0= no itch and 10= worst itch imaginable. Higher scores indicated worse itch. Full Analysis Set (FAS) comprised of all randomised subjects who received at least one dose of study intervention. Here, 'Number of Subjects Analysed' signifies subjects evaluable for this end point.

End point type	Primary

End point timeframe:

Week 2

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	357	364		
Units: Percentage of subjects				
number (confidence interval 95%)	48.2 (43.0 to 53.4)	25.5 (21.1 to 30.0)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	721
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	< 0.0001 [2]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Estimate of difference
Point estimate	22.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.8
upper limit	29.5

Notes:

[1] - The estimate and confidence interval (CI) for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.
[2] - Cochran-Mantel-Haenszel (CMH) method adjusted by baseline disease severity.

Primary: Percentage of Subjects Achieving >= 90% Improvement from Baseline in Eczema Area and Severity Index (EASI-90) Response at Week 4

End point title	Percentage of Subjects Achieving >= 90% Improvement from Baseline in Eczema Area and Severity Index (EASI-90) Response at Week 4

End point description:

Severity of clinical signs of AD lesions (erythema, induration/papulation, excoriation and lichenification) were scored separately for each of 4 body regions (head and neck, upper limbs, trunk) and lower limbs) on a 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score=% BSA with AD in body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+ExI+Ll); A = EASI area score; E = erythema; I = induration/papulation; Ex = excoriation; L = lichenification; h = head and neck; u = upper limbs; t = trunk; l = lower limbs. Total EASI score ranged from 0.0 to 72.0, with higher scores indicating greater severity of AD. FAS comprised of all randomised subjects who received at least one dose of study intervention. Here, 'Number of Subjects Analysed' signifies subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Week 4

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	364		
Units: Percentage of subjects				
number (confidence interval 95%)	28.5 (23.8 to 33.2)	14.6 (10.9 to 18.2)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	718
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001 [3]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Estimate of difference
Point estimate	14.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.2
upper limit	20

Notes:

[3] - CMH method adjusted by baseline disease severity.

Secondary: Percentage of Subjects Achieving EASI-90 Response at Week 16

End point title	Percentage of Subjects Achieving EASI-90 Response at Week 16

End point description:

Severity of clinical signs of AD lesions (erythema, induration/papulation, excoriation and lichenification) were scored separately for each of 4 body regions (head and neck, upper limbs, trunk) and lower limbs) on a 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score=% BSA with AD in body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+ExI+Ll); A = EASI area score; E = erythema; I = induration/papulation; Ex = excoriation; L = lichenification; h = head and neck; u = upper limbs; t = trunk; l = lower limbs. Total EASI score ranged from 0.0 to 72.0, with higher scores indicating greater severity of AD. FAS comprised of all randomised subjects who received at least one dose of study intervention. Here, 'Number of Subjects Analysed' signifies subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 16

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	357	360		
Units: Percentage of subjects				
number (confidence interval 95%)	54.3 (49.2 to 59.5)	41.9 (36.8 to 47.0)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	717
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0008 [4]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Estimate of difference
Point estimate	12.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.3
upper limit	19.7

Notes:

[4] - CMH method adjusted by baseline disease severity.

Secondary: Percentage of Subjects Achieving EASI-90 Response at Weeks 2, 8, 12, 20 and 26

End point title	Percentage of Subjects Achieving EASI-90 Response at Weeks 2, 8, 12, 20 and 26

End point description:

Severity of clinical signs of AD lesions (erythema, induration/papulation, excoriation and lichenification) were scored separately for each of 4 body regions (head and neck, upper limbs, trunk) and lower limbs) on a 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score=% BSA with AD in body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+Exl+Ll); A = EASI area score; E = erythema; I = induration/papulation; Ex = excoriation; L = lichenification; h = head and neck; u = upper limbs; t = trunk; l = lower limbs. Total EASI score ranged from 0.0 to 72.0, with higher scores indicating greater severity of AD. FAS comprised of all randomised subjects who received at least one dose of study intervention. Here, 'n' signifies participants evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Week 2, 8, 12, 20 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 2; n=361, 362	11.6 (8.3 to 14.9)	7.2 (4.5 to 9.8)		
Week 8; n=355, 362	45.4 (40.2 to 50.5)	25.4 (20.9 to 29.9)		
Week 12; n=359, 363	47.6 (42.5 to 52.8)	33.6 (28.7 to 38.5)		
Week 20; n=356, 363	58.4 (53.3 to 63.5)	45.7 (40.6 to 50.9)		
Week 26; n=348, 361	54.6 (49.4 to 59.8)	47.6 (42.5 to 52.8)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 2. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	8.7

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 8. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	20
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.2
upper limit	26.9

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 12. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	14

Confidence interval	
level	95 %
sides	2-sided
lower limit	6.9
upper limit	21.1

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 20. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	12.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.5
upper limit	20

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 26. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	6.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	14.3

Secondary: Percentage of Subjects Achieving >= 75% Improvement from Baseline in EASI (EASI-75) Response at Weeks 2, 4, 8, 12, 16, 20 and 26

End point title	Percentage of Subjects Achieving >= 75% Improvement from Baseline in EASI (EASI-75) Response at Weeks 2, 4, 8, 12, 16, 20 and 26

End point description:

Severity of clinical signs of AD lesions (erythema, induration/papulation, excoriation and lichenification)

were scored separately for each of 4 body regions (head and neck, upper limbs, trunk) and lower limbs) on a 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score=% BSA with AD in body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+ExI+Ll); A = EASI area score; E = erythema; I = induration/papulation; Ex = excoriation; L = lichenification; h = head and neck; u = upper limbs; t = trunk; l = lower limbs. Total EASI score ranged from 0.0 to 72.0, with higher scores indicating greater severity of AD. FAS comprised of all randomised subjects who received at least one dose of study intervention. Here, 'n' signifies participants evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Week 2, 4, 8, 12, 16, 20 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 2; n=361, 362	29.4 (24.7 to 34.1)	21.3 (17.1 to 25.5)		
Week 4; n=354, 364	57.6 (52.5 to 62.8)	36.8 (31.9 to 41.8)		
Week 8; n=355, 362	71.0 (66.3 to 75.7)	52.8 (47.6 to 57.9)		
Week 12; n=359, 363	76.3 (71.9 to 80.7)	61.4 (56.4 to 66.4)		
Week 16; n=357, 360	77.3 (73.0 to 81.7)	67.8 (63.0 to 72.6)		
Week 20; n=356, 363	76.1 (71.7 to 80.6)	71.1 (66.4 to 75.7)		
Week 26; n=348, 361	73.0 (68.3 to 77.7)	72.3 (67.7 to 76.9)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 2. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	14.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 8. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	18.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.4
upper limit	25.3

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 4. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	20.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.8
upper limit	28

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 12. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	14.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	8.2
upper limit	21.5

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 16. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	9.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	3
upper limit	16

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 20. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	11.5

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 26. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.9
upper limit	7.2

Secondary: Percentage of Subjects Achieving Investigator's Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' and >=2 Points Improvement from Baseline up to Week 26

End point title	Percentage of Subjects Achieving Investigator's Global Assessment (IGA) Score of 'Clear' or 'Almost Clear' and >=2 Points Improvement from Baseline up to Week 26

End point description:

IGA=severity of AD on a 5 point scale (0 to 4, higher scores=more severity). Scores: 0= clear, except any residual discoloration (post-inflammatory hyperpigmentation and/or hypopigmentation); 1= almost clear, AD not fully cleared- light pink residual lesions (except post-inflammatory hyperpigmentation), just perceptible erythema, papulation/induration lichenification, excoriation, and no oozing/crusting; 2= mild AD with light red lesions, slight but definite erythema, papulation/induration, lichenification, excoriation and no oozing/crusting; 3= moderate AD with red lesions, moderate erythema, papulation/induration, lichenification, excoriation and slight oozing/crusting; 4= severe AD with deep dark red lesions, severe erythema, papulation/induration, lichenification, excoriation and moderate to severe oozing/crusting. FAS comprised of all randomised subjects who received at least one dose of study intervention. Here, 'n' signifies subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Week 2, 4, 8, 12, 16, 20 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 2; n=361, 362	14.4 (10.8 to 18.0)	7.2 (4.5 to 9.8)		
Week 4; n=353, 364	38.0 (32.9 to 43.0)	17.6 (13.7 to 21.5)		
Week 8; n=355, 362	50.1 (44.9 to 55.3)	30.9 (26.2 to 35.7)		
Week 12; n=359, 364	51.8 (46.6 to 57.0)	36.0 (31.1 to 40.9)		
Week 16; n=358, 360	55.3 (50.2 to 60.5)	42.5 (37.4 to 47.6)		
Week 20; n=355, 364	60.0 (54.9 to 65.1)	50.8 (45.7 to 56.0)		
Week 26; n=347, 362	55.6 (50.4 to 60.8)	51.1 (46.0 to 56.3)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 2. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	7.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.8
upper limit	11.7

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 4. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	20.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.3
upper limit	26.9

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 8. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	19.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.5
upper limit	26.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 12. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	15.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.7
upper limit	23

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 16. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	13
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.9
upper limit	20.2

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 20. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	9.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	16.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 26. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.8
upper limit	11.8

Secondary: Percentage of Subjects Achieving PP-NRS4 from Baseline at Days 2 to 15

End point title	Percentage of Subjects Achieving PP-NRS4 from Baseline at Days 2 to 15

End point description:

The severity of itch (pruritus) due to AD was assessed using the PP-NRS, a validated horizontal NRS. Subjects were asked to assess their worst itching due to AD over the past 24 hours on an NRS with scale ranging from 0 to 10, where 0= no itch and 10= worst itch imaginable. Higher scores indicated worse itch. FAS comprised of all randomised subjects who received at least one dose of study intervention. Here, 'n' signifies subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Day 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 and 15

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 2; n=319, 317	11.0 (7.5 to 14.4)	3.8 (1.7 to 5.9)		
Day 3; n=345, 350	15.1 (11.3 to 18.8)	8.6 (5.6 to 11.5)		
Day 4; n=349, 356	22.1 (17.7 to 26.4)	10.7 (7.5 to 13.9)		
Day 5; n=352, 353	26.4 (21.8 to 31.0)	11.9 (8.5 to 15.3)		
Day 6; n=348, 348	28.4 (23.7 to 33.2)	15.5 (11.7 to 19.3)		
Day 7; n=347, 355	33.1 (28.2 to 38.1)	13.2 (9.7 to 16.8)		
Day 8; n=353, 347	36.3 (31.2 to 41.3)	14.1 (10.5 to 17.8)		
Day 9; n=348, 350	38.5 (33.4 to 43.6)	16.9 (12.9 to 20.8)		
Day 10; n=345, 353	40.0 (34.8 to 45.2)	18.7 (14.6 to 22.8)		
Day 11; n=349, 347	40.1 (35.0 to 45.3)	20.2 (16.0 to 24.4)		
Day 12; n=347, 351	41.5 (36.3 to 46.7)	20.2 (16.0 to 24.4)		
Day 13; n=348, 354	44.0 (38.8 to 49.2)	21.5 (17.2 to 25.7)		
Day 14; n=347, 354	45.5 (40.3 to 50.8)	23.2 (18.8 to 27.6)		
Day 15; n=350, 359	48.6 (43.3 to 53.8)	25.6 (21.1 to 30.1)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Day 2. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	7.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.1
upper limit	11.1

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Day 3. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	6.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.7
upper limit	11.3

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Day 4. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	11.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	6
upper limit	16.8

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Day 5. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	14.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	8.8
upper limit	20.3

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Day 6. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	12.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.9
upper limit	19

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Day 7. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	19.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.8
upper limit	26

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Day 8. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	22.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.9
upper limit	28.3

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Day 10. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of other
Point estimate	21.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.7
upper limit	27.9

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Day 9. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	21.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.2
upper limit	28.1

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Day 11. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	20
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.3
upper limit	26.6

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Day 12. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	21.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.6
upper limit	27.9

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Day 14. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	22.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.6
upper limit	29.2

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Day 13. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	22.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.8
upper limit	29.2

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Day 15. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	22.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	16
upper limit	29.9

Secondary: Percentage of Subjects Achieving PP-NRS4 from Baseline at Week 4, 8, 12, 16, 20 and 26

End point title	Percentage of Subjects Achieving PP-NRS4 from Baseline at Week 4, 8, 12, 16, 20 and 26

End point description:

The severity of itch (pruritus) due to AD was assessed using the PP-NRS, a validated horizontal NRS. Subjects were asked to assess their worst itching due to AD over the past 24 hours on an NRS with scale ranging from 0 to 10, where 0= no itch and 10= worst itch imaginable. Higher scores indicated worse itch. FAS comprised of all randomised subjects who received at least one dose of study intervention. Here, 'n' signifies subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 20 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4; n=356, 363	58.1 (53.0 to 63.3)	40.8 (35.7 to 45.8)		
Week 8; n=357, 364	65.8 (60.9 to 70.7)	52.7 (47.6 to 57.9)		
Week 12; n=356, 364	66.0 (61.1 to 70.9)	61.5 (56.5 to 66.5)		
Week 16; n=357, 363	67.2 (62.4 to 72.1)	63.6 (58.7 to 68.6)		
Week 20; n=357, 364	65.3 (60.3 to 70.2)	63.2 (58.2 to 68.1)		
Week 26; n=354, 363	68.1 (63.2 to 72.9)	63.1 (58.1 to 68.0)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 4. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	17.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.1
upper limit	24.5

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 8. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	13
Confidence interval	
level	95 %
sides	2-sided
lower limit	6
upper limit	20.1

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 12. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	4.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	11.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 16. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	3.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	10.5

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 20. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.9
upper limit	9

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 26. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	11.9

Secondary: Time to Achieve >=4 Points Improvement in PP-NRS4

End point title	Time to Achieve >=4 Points Improvement in PP-NRS4

End point description:

The severity of itch (pruritus) due to AD was assessed using the PP-NRS, a validated horizontal NRS. Subjects were asked to assess their worst itching due to AD over the past 24 hours on an NRS with scale ranging from 0 to 10, where 0= no itch and 10= worst itch imaginable. Higher scores indicated worse itch. FAS comprised of all randomised subjects who received at least one dose of study intervention. Here, 'Number of Subjects Analysed' signifies subjects evaluable for this end point.

End point type	Secondary

End point timeframe:

Baseline (Day 1) up to Week 30

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	313	303		
Units: Days				
median (confidence interval 95%)	11.0 (9.0 to 14.0)	25.0 (21.0 to 30.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in the Percentage (%) Body Surface Area (BSA) Affected at Week 2, 4, 8, 12, 16, 20 and 26

End point title	Percent Change from Baseline in the Percentage (%) Body Surface Area (BSA) Affected at Week 2, 4, 8, 12, 16, 20 and 26

End point description:

Extent (%) of body region involvement with AD was determined using handprint method. Number of handprints (size of subject's hand with fingers in a closed position) fitting in affected area of a body region was estimated. 4 body regions were evaluated: head and neck, upper limbs, trunk (including axillae and groin/genitals) and lower limbs (including buttocks). Total number of handprints=10 for head and neck, 20 for upper limbs, 30 for trunk and 40 for lower limbs. Surface area of body region equivalent to 1 handprint: 1 handprint =10% for head and neck, 5% for upper limbs, 3.33% for trunk and 2.5% for lower limbs. Percent BSA for a body region= total number of handprints in a body region * % surface area equivalent to 1 handprint. Overall % BSA for an individual was derived as sum of % BSA across all 4 body regions and ranged from 0 to 100%, with higher values representing greater severity of AD. FAS=all randomised subjects who received at least one dose of study intervention.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 2, 4, 8, 12, 16, 20 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Percent change				
least squares mean (confidence interval 95%)				
Week 2	-42.7 (-46.0 to -39.4)	-33.4 (-36.7 to -30.0)		
Week 4	-62.0 (-65.5 to -58.5)	-49.5 (-53.0 to -46.1)		
Week 8	-74.0 (-77.2 to -70.7)	-62.8 (-66.0 to -59.7)		
Week 12	-78.8 (-81.9 to -75.7)	-69.4 (-72.5 to -66.4)		
Week 16	-80.6 (-83.5 to -77.8)	-73.7 (-76.5 to -70.9)		
Week 20	-82.2 (-84.8 to -79.6)	-76.9 (-79.5 to -74.3)		
Week 26	-82.3 (-85.0 to -79.6)	-79.0 (-81.6 to -76.3)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 2. Analysis was performed using Mixed Model Repeated Measure (MMRM) with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-9.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14
upper limit	-4.6

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 4. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-12.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.4
upper limit	-7.6

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 8. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-11.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.6
upper limit	-6.6

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-9.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.7
upper limit	-5.1

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-6.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.9
upper limit	-2.9

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 20. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-5.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9
upper limit	-1.7

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	0.4

Secondary: Percent Change from Baseline in the SCORing Atopic Dermatitis (SCORAD) Total Score at Week 2, 4, 8, 12, 16, 20 and 26

End point title	Percent Change from Baseline in the SCORing Atopic Dermatitis (SCORAD) Total Score at Week 2, 4, 8, 12, 16, 20 and 26

End point description:

SCORAD=scoring index for AD combining extent (A), severity (B) and subjective symptoms (C). For A, rule of 9 used to calculate BSA affected by AD as % of whole BSA for each body region- head and neck 9%; upper limbs 9% each; lower limbs 18% each; anterior trunk 18%; back 18%; genitals 1%. Score of each body region added to determine A (range: 0-100). B: severity of each sign (erythema; edema/papulation; oozing/crusting; excoriation; skin thickening; dryness) was assessed as none (0), mild (1), moderate (2), severe (3); severity scores were added to give B (range: 0-18). C: pruritus and sleep loss, each scored by subject/caregiver using visual analog scale (VAS) where, 0=no itch/no sleep loss and 10=worst imaginable itch/sleep loss, higher scores=worse symptoms. Scores for itch and sleep loss were added to give 'C' (range: 0-20). SCORAD total score =A/5+7*B/2+C; range (0-103);higher values=worse outcome. FAS=all randomised subjects who received at least one dose of study intervention.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 2, 4, 8, 12, 16, 20 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Percent change				
least squares mean (confidence interval 95%)				
Week 2	-44.5 (-47.0 to -42.1)	-33.5 (-35.9 to -31.0)		
Week 4	-59.6 (-61.9 to -57.3)	-46.8 (-49.1 to -44.5)		
Week 8	-65.8 (-68.2 to -63.4)	-55.6 (-58.0 to -53.3)		
Week 12	-67.9 (-70.2 to -65.6)	-60.6 (-62.9 to -58.3)		
Week 16	-70.6 (-72.8 to -68.3)	-64.4 (-66.7 to -62.2)		
Week 20	-71.8 (-74.1 to -69.4)	-66.8 (-69.1 to -64.5)		
Week 26	-71.5 (-73.9 to -69.1)	-68.2 (-70.6 to -65.9)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 2. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.5
upper limit	-7.6

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 8. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-10.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.6
upper limit	-6.8

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 4. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-12.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16
upper limit	-9.5

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-7.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.5
upper limit	-4.1

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-6.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.3
upper limit	-3

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 20. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.2
upper limit	-1.7

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.6
upper limit	0.1

Secondary: Change from Baseline in Total Anxiety Score Measured Using the Hospital Anxiety and Depression Scale (HADS) at Week 12,16 and 26

End point title	Change from Baseline in Total Anxiety Score Measured Using the Hospital Anxiety and Depression Scale (HADS) at Week 12,16 and 26

End point description:

HADS was a validated 14-item questionnaire to assess states of anxiety and depression over the past week. HADS consisted of 2 subscales: HADS-Anxiety (HADS-A) scale and HADS-Depression (HADS-D) scale, each of which comprised of 7 items. Each item was rated on a 4-point scale, with scores ranging from 0 to 3, where higher scores indicated more anxiety/depression symptoms. HADS-A assessed state of generalized anxiety (anxious mood, restlessness, anxious thoughts, panic attacks). HADS-A total score was calculated as the sum of all 7 items with score ranging from 0 (no presence of anxiety) to 21 (severe feeling of anxiety); higher score indicated greater severity of anxiety. FAS comprised of all randomised subjects who received at least one dose of study intervention.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 12, 16 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Week 12	-0.8 (-1.1 to -0.5)	-0.8 (-1.1 to -0.6)		
Week 16	-1.1 (-1.3 to -0.8)	-1.2 (-1.4 to -0.9)		
Week 26	-1.1 (-1.4 to -0.7)	-1.2 (-1.5 to -0.9)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	0.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.6

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.5

Secondary: Change from Baseline in Total Depression Score Measured Using the HADS at Week 12,16 and 26

End point title	Change from Baseline in Total Depression Score Measured Using the HADS at Week 12,16 and 26

End point description:

HADS was a validated 14-item questionnaire to assess states of anxiety and depression over the past week. HADS consisted of 2 subscales: HADS-A scale and HADS-D scale, each of which comprised of 7

items. Each item was rated on a 4-point scale, with scores ranging from 0 to 3, where higher scores indicated more anxiety/depression symptoms. HADS-D assessed the state of lost interest and diminished pleasure response (lowering of hedonic tone). HADS-D: total score was calculated as the sum of all 7 items with score ranging from 0 (no presence of depression) to 21 (severe feeling of depression); higher score indicated greater severity of depression symptoms. FAS comprised of all randomised subjects who received at least one dose of study intervention.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 12, 16 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Week 12	-0.7 (-1.0 to -0.5)	-0.7 (-1.0 to -0.5)		
Week 16	-0.8 (-1.0 to -0.5)	-0.9 (-1.1 to -0.7)		
Week 26	-0.8 (-1.0 to -0.5)	-1.0 (-1.3 to -0.8)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.3

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.6

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.5

Secondary: Change from Baseline in Dermatology Life Quality Index (DLQI) Total Score at Week 2, 12, 16, 20 and 26

End point title	Change from Baseline in Dermatology Life Quality Index (DLQI) Total Score at Week 2, 12, 16, 20 and 26

End point description:

DLQI is a 10-item questionnaire that measured the impact of skin disease. Each question was evaluated on a 4-point scale (range 0 to 3) where, 0 = not at all, 1= a little, 2= a lot, 3= very much, where higher scores indicated more impact on quality of life. Scores from all 10 questions were added up to give DLQI total score, ranging from 0 (not at all) to 30 (very much). Higher scores indicated more impact on quality of life of subjects. FAS comprised of all randomised subjects who received at least one dose of study intervention. Here, 'Number of Subjects Analysed' signifies subjects evaluable for this end point.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 2, 12, 16, 20 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	361	363		
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Week 2	-8.6 (-9.1 to -8.2)	-6.7 (-7.1 to -6.2)		
Week 12	-10.7 (-11.1 to -10.2)	-9.7 (-10.1 to -9.3)		
Week 16	-10.8 (-11.2 to -10.4)	-10.0 (-10.5 to -9.6)		
Week 20	-10.8 (-11.2 to -10.3)	-10.1 (-10.6 to -9.7)		
Week 26	-10.3 (-10.8 to -9.9)	-10.0 (-10.5 to -9.6)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 2. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	724
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	-1.3

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	724
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	-0.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	724
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	-0.2

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	724
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 20. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	724
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2
upper limit	0

Secondary: Change from Baseline in EuroQol Quality of Life 5-Dimension 5-Level (EQ-5D-5L) Visual Analog Scale (VAS) Score at Week 12, 16 and 26

End point title	Change from Baseline in EuroQol Quality of Life 5-Dimension 5-Level (EQ-5D-5L) Visual Analog Scale (VAS) Score at Week 12, 16 and 26

End point description:

The EQ-5D-5L is a self-reported health status questionnaire that consisted of six questions used to calculate a health utility score. There were two components to the EQ-5D-5L: a five-item health state profile that assessed mobility, self-care, usual activities, pain/discomfort, and anxiety/depression used to obtain an Index Utility Score, as well as a VAS that measured health state. EQ-5D VAS was used to record subject’s rating for his/her current health-related quality of life state on a vertical VAS with scores ranging from 0 to 100, where 0 = worst imaginable health state and 100 = best imaginable health state. FAS comprised of all randomised subjects who received at least one dose of study intervention. Here, 'Number of Subjects Analysed' signifies subjects evaluable for this end point.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 12, 16 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	364		
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Week 12	12.370 (10.917 to 13.822)	11.552 (10.123 to 12.981)		
Week 16	12.567 (11.015 to 14.118)	10.474 (8.951 to 11.997)		
Week 26	13.484 (11.982 to 14.985)	14.300 (12.836 to 15.764)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0.818
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.22
upper limit	2.856

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-0.816
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.914
upper limit	1.281

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	726
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	2.093
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.081
upper limit	4.267

Secondary: Change from Baseline in Patient-Oriented Eczema Measure (POEM) Total Score at Week 12, 16 and 26

End point title	Change from Baseline in Patient-Oriented Eczema Measure (POEM) Total Score at Week 12, 16 and 26

End point description:

POEM was a 7-item patient reported outcome measure used to assess the impact of AD (dryness, itching, flaking, cracking, sleep loss, bleeding and weeping) over the past week. Each item was scored as: no days=0, 1-2 days=1, 3-4 days=2, 5-6 days=3 and every day=4. The item scores were added to provide a total score ranging from 0 to 28, where higher score indicated greater severity. FAS comprised of all randomised subjects who received at least one dose of study intervention.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 12, 16 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Week 12	-14.2 (-14.9 to -13.6)	-12.6 (-13.3 to -12.0)		
Week 16	-14.2 (-14.8 to -13.6)	-12.8 (-13.4 to -12.2)		
Week 26	-13.8 (-14.5 to -13.1)	-13.4 (-14.0 to -12.7)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	-0.7

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	-0.5

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	0.5

Secondary: Change from Baseline in Medical Outcomes Study – Sleep Scale (MOS-Sleep Scale) at Week 12, 16 and 26

End point title	Change from Baseline in Medical Outcomes Study – Sleep Scale (MOS-Sleep Scale) at Week 12, 16 and 26

End point description:

The MOS Sleep Scale is a 12-item measure that is segregated into subscales addressing seven sleep domains (i.e. sleep disturbance, snoring, short of breath or headache, adequacy of sleep, somnolence, sleep problems index I and sleep problems index II). An additional single item assessed quantity of sleep. Each of the sleep domains were scored on a range of 0-100, and higher scores indicated worse outcomes. The quantity of sleep scores ranged from 0 to 24 (number of hours slept). Change from baseline scores for each individual sleep domain and quantity of sleep are reported in this outcome measure. FAS comprised of all randomised subjects who received at least one dose of study intervention.

End point type	Secondary

End point timeframe:
Baseline (Day 1), Week 12, 16 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Quantity Hours Slept Score: Week 12	0.7 (0.5 to 0.9)	0.5 (0.2 to 0.7)		
Quantity Hours Slept Score: Week 16	0.6 (0.3 to 0.8)	0.5 (0.3 to 0.7)		
Quantity Hours Slept Score: Week 26	0.5 (0.3 to 0.7)	0.4 (0.2 to 0.6)		
Short of Breath or Headache score: Week 12	-0.7 (-2.2 to 0.9)	-1.9 (-3.4 to -0.4)		
Short of Breath or Headache score: Week 16	-1.2 (-2.7 to 0.3)	-1.3 (-2.8 to 0.2)		
Short of Breath or Headache score: Week 26	-2.0 (-3.5 to -0.6)	-2.6 (-4.0 to -1.2)		
Snoring Score: Week 12	-5.3 (-7.0 to -3.6)	-3.5 (-5.2 to -1.8)		
Snoring Score: Week 16	-4.9 (-6.6 to -3.1)	-4.0 (-5.7 to -2.3)		
Snoring Score: Week 26	-3.9 (-5.7 to -2.0)	-4.7 (-6.5 to -2.9)		
Sleep Disturbance Score: Week 12	-20.5 (-22.3 to -18.8)	-16.4 (-18.1 to -14.7)		
Sleep Disturbance Score: Week 16	-21.5 (-23.2 to -19.7)	-17.7 (-19.4 to -16.0)		
Sleep Disturbance Score: Week 26	-21.2 (-23.0 to -19.5)	-19.5 (-21.2 to -17.8)		
Sleep Adequacy Score: Week 12	13.9 (12.1 to 15.8)	12.9 (11.1 to 14.7)		
Sleep Adequacy Score: Week 16	15.7 (13.9 to 17.4)	12.7 (11.0 to 14.5)		
Sleep Adequacy Score: Week 26	14.0 (12.1 to 15.8)	13.2 (11.4 to 15.1)		
Sleep Somnolence Score: Week 12	-7.7 (-9.1 to -6.2)	-6.9 (-8.3 to -5.5)		
Sleep Somnolence Score: Week 16	-9.8 (-11.3 to -8.4)	-7.4 (-8.8 to -6.0)		
Sleep Somnolence Score: Week 26	-9.9 (-11.3 to -8.5)	-7.6 (-9.0 to -6.2)		
Sleep Problems Index I Score: Week 12	-12.1 (-13.4 to -10.8)	-10.9 (-12.2 to -9.6)		
Sleep Problems Index I Score: Week 16	-13.3 (-14.5 to -12.0)	-11.0 (-12.2 to -9.8)		
Sleep Problems Index I Score: Week 26	-12.9 (-14.2 to -11.7)	-12.1 (-13.3 to -10.9)		
Sleep Problems Index II Score: Week 12	-14.4 (-15.7 to -13.1)	-12.2 (-13.5 to -10.9)		
Sleep Problems Index II Score: Week 16	-15.7 (-17.0 to -14.4)	-12.8 (-14.0 to -11.5)		
Sleep Problems Index II Score: Week 26	-15.4 (-16.7 to -14.1)	-14.0 (-15.2 to -12.7)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Quantity of hours slept: Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.6

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Quantity of hours slept: Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Quantity of hours slept: Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Short of Breath or Headache score: Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	3.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Short of Breath or Headache score: Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	2.2

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Short of Breath or Headache score: Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	2.6

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Snoring score: Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	0.5

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Snoring score: Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	1.5

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Snoring score: Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	3.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Sleep disturbance score: Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.6
upper limit	-1.6

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Sleep disturbance score: Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.2
upper limit	-1.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Sleep disturbance score: Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.1
upper limit	0.7

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Sleep adequacy score: Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	5.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description: Sleep adequacy score: Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	3.6

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description: Sleep somnolence score: Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.8
upper limit	1.3

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description: Sleep adequacy score: Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	3.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Sleep somnolence score: Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	-0.3

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Sleep somnolence score: Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.4
upper limit	-0.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Sleep Problems Index I score: Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	0.7

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Sleep Problems Index I score: Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	-0.5

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Sleep Problems Index I score: Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-0.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	0.9

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Sleep Problems Index II score: Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	-1.1

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Sleep Problems Index II score: Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	-0.3

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Sleep Problems Index II score: Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	0.4

Secondary: Change from Baseline in Skin Pain NRS at Week 2, 12, 16, 20 and 26

End point title	Change from Baseline in Skin Pain NRS at Week 2, 12, 16, 20 and 26

End point description:

The skin pain NRS was a patient reported outcome where subjects were asked to rate the "worst skin pain" in the past 24 hours on a 11-point scale from 0=no skin pain to 10=worst skin pain imaginable. Higher scores indicated worse pain. FAS comprised of all randomised subjects who received at least one dose of study intervention.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 2, 12, 16, 20 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Week 2	-3.7 (-3.9 to -3.4)	-2.6 (-2.8 to -2.3)		
Week 12	-4.5 (-4.7 to -4.2)	-4.0 (-4.3 to -3.8)		
Week 16	-4.4 (-4.7 to -4.2)	-4.2 (-4.4 to -4.0)		
Week 20	-4.8 (-5.0 to -4.5)	-4.5 (-4.7 to -4.2)		
Week 26	-4.5 (-4.8 to -4.3)	-4.3 (-4.6 to -4.1)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 12. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	-0.1

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 2. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	-0.8

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 20. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	0

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 26. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	0.1

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 16. Analysis was performed using MMRM with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	0.1

Secondary: Medicated topical background therapy-free days

End point title	Medicated topical background therapy-free days

End point description:

Medicated topical background therapy-free days was defined as number of days where a subject maintained a response of EASI-90 or greater without the use of medicated topical background therapy. FAS comprised of all randomised subjects who received at least one dose of study intervention.

End point type	Secondary

End point timeframe:

Day 1 up to Week 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Days				
least squares mean (confidence interval 95%)	51.4 (46.0 to 56.8)	33.3 (27.9 to 38.7)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Analysis was performed using analysis of covariance (ANCOVA) model including treatment as a main effect and baseline disease severity as covariates.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Least square mean difference
Point estimate	18.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.5
upper limit	25.7

Secondary: Percentage of Subjects Achieving >=4 Points Improvement from Baseline in DLQI at Week 2, 12, 16, 20 and 26

End point title	Percentage of Subjects Achieving >=4 Points Improvement from Baseline in DLQI at Week 2, 12, 16, 20 and 26

End point description:

DLQI was a 10-item questionnaire that measured the impact of skin disease. Each question was evaluated on a 4-point scale (range 0 to 3) where, 0 = not at all, 1= a little, 2= a lot, 3= very much, where higher scores indicated more impact on quality of life. Scores from all 10 questions were added up to give DLQI total score range from 0 (not at all) to 30 (very much). Higher scores indicated more impact on quality of life of subjects. FAS comprised of all randomised subjects who received at least one dose of study intervention. Here, 'n' signifies subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Week 2, 12, 16, 20 and 26

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 2; n=342, 351	81.3 (77.2 to 85.4)	67.5 (62.6 to 72.4)		
Week 12; n=343, 350	85.4 (81.7 to 89.2)	81.4 (77.4 to 85.5)		
Week 16; n=342, 349	82.7 (78.7 to 86.8)	84.2 (80.4 to 88.1)		
Week 20; n=341, 350	81.8 (77.7 to 85.9)	83.7 (79.8 to 87.6)		
Week 26; n=334, 349	76.6 (72.1 to 81.2)	80.8 (76.7 to 84.9)		

Statistical analyses

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 2. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	13.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.3
upper limit	20.1

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W

Statistical analysis description:

Week 12. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.

Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	3.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	9.4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 16. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	4

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 20. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W
Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.6
upper limit	3.6

Statistical analysis title	Abrocitinib 200 mg QD vs Dupilumab 300 mg Q2W
Statistical analysis description:	
Week 26. The estimate and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions.	
Comparison groups	Abrocitinib 200 mg QD v Dupilumab 300 mg Q2W

Number of subjects included in analysis	727
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Estimate of difference
Point estimate	-4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.3
upper limit	1.9

Other pre-specified: Number of Subjects with Treatment Emergent Adverse Events (TEAEs)

End point title	Number of Subjects with Treatment Emergent Adverse Events (TEAEs)

End point description:

An AE was any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE was considered a TEAE if the event started on or after the first dosing day until 28 days post last dose of study drug. AEs included both serious and non-serious AEs. Safety population comprised of all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

End point type	Other pre-specified

End point timeframe:

From start of study intervention to 28 days post last dose of study intervention (Up to Week 30)

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Subjects	268	239		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects with Serious Adverse Events (SAEs) and AEs Leading to Study Discontinuation

End point title	Number of Subjects with Serious Adverse Events (SAEs) and AEs Leading to Study Discontinuation

End point description:

An SAE was defined as any untoward medical occurrence that, at any dose: resulted in death; was life-threatening; required inpatient hospitalization or prolongation of existing hospitalization; resulted in persistent disability/incapacity; a congenital anomaly/birth defect and other important medical events. Safety population comprised of all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

End point type	Other pre-specified

End point timeframe:

From start of study intervention to 28 days post last dose of study intervention (Up to Week 30)

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Subjects				
SAEs	6	6		
AEs Leading to Study Discontinuation	12	9		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects with Laboratory Abnormalities Meeting Pre-Defined Criteria

End point title	Number of Subjects with Laboratory Abnormalities Meeting Pre-Defined Criteria

End point description:

The pre-defined criteria for laboratory parameters included: haemoglobin (<9 grams per decilitre or decreases to >=2 below baseline); platelets (<75*10^3 cells per millimetre cube [mm^3]); lymphocytes (<0.5*10^3 cells per mm^3); neutrophils (<1*10^3 cells per mm^3); aspartate aminotransferase and alanine aminotransferase (>3* upper limit of normal). Safety population comprised of all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

End point type	Other pre-specified

End point timeframe:

From start of study intervention to 28 days post last dose of study intervention (Up to Week 30)

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Subjects	38	10		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects with Clinically Significant Change from Baseline in Vital Signs

End point title	Number of Subjects with Clinically Significant Change from Baseline in Vital Signs

End point description:

Vital signs including temperature, systolic and diastolic blood pressure, and pulse rate were measured in a seated position after 5 minutes rest. Clinically significant change from baseline in vital signs were determined by the investigator. Safety population comprised of all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

End point type	Other pre-specified

End point timeframe:

From start of study intervention to 28 days post last dose of study intervention (Up to Week 30)

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects with Clinically Significant Change from Baseline in Electrocardiogram (ECG) Data

End point title	Number of Subjects with Clinically Significant Change from Baseline in Electrocardiogram (ECG) Data

End point description:

A single 12-lead ECG was performed after the subject has rested for at least 10 minutes quietly in the supine position. Clinically significant change from baseline in ECG data was determined by the investigator. Safety population comprised of all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

End point type	Other pre-specified

End point timeframe:

From start of study intervention to 28 days post last dose of study intervention (Up to Week 30)

End point values	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	362	365		
Units: Subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From start of study intervention up to 28 days after last dose of study intervention (Up to Week 30)

Adverse event reporting additional description:

An AE term may be reported as both a serious and non-serious AE, but are distinct events. An AE may be serious for 1 subject and non-serious for another subject, or a subject may have experienced both a serious and non-serious episode of the same event.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Abrocitinib 200 mg QD

Reporting group description:

Subjects were administered abrocitinib 200 mg (2 x 100 mg) oral tablets once daily from Day 1 to Week 26 along with dupilumab-matching placebo administered as a subcutaneous injection Q2W until Week 24. Subjects were followed for up to 4 weeks post last dose of study intervention.

Reporting group title	Dupilumab 300 mg Q2W

Reporting group description:

Subjects were administered dupilumab 300 mg as a subcutaneous injection Q2W until Week 24 along with abrocitinib-matching placebo oral tablets administered once daily from Day 1 to Week 26. Subjects were followed for up to 4 weeks post last dose of study intervention.

Serious adverse events	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 362 (1.66%)	6 / 365 (1.64%)	
number of deaths (all causes)	2	0	
number of deaths resulting from adverse events			
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 362 (0.00%)	1 / 365 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Upper limb fracture			
subjects affected / exposed	1 / 362 (0.28%)	0 / 365 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			

Cardio-respiratory arrest			
subjects affected / exposed	1 / 362 (0.28%)	0 / 365 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Nervous system disorders			
Haemorrhage intracranial			
subjects affected / exposed	1 / 362 (0.28%)	0 / 365 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 362 (0.28%)	0 / 365 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 362 (0.00%)	1 / 365 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 362 (0.00%)	1 / 365 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Nephrotic syndrome			
subjects affected / exposed	0 / 362 (0.00%)	1 / 365 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Musculoskeletal chest pain			
subjects affected / exposed	0 / 362 (0.00%)	1 / 365 (0.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			

subjects affected / exposed	0 / 362 (0.00%)	1 / 365 (0.27%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 362 (0.28%)	0 / 365 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	1 / 362 (0.28%)	0 / 365 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 362 (0.28%)	0 / 365 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Abrocitinib 200 mg QD	Dupilumab 300 mg Q2W	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	203 / 362 (56.08%)	144 / 365 (39.45%)	
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	14 / 362 (3.87%)	13 / 365 (3.56%)	
occurrences (all)	14	13	
Natural killer cell count decreased			
subjects affected / exposed	10 / 362 (2.76%)	0 / 365 (0.00%)	
occurrences (all)	13	0	
SARS-CoV-2 test positive			
subjects affected / exposed	15 / 362 (4.14%)	13 / 365 (3.56%)	
occurrences (all)	15	13	
Weight increased			

subjects affected / exposed	8 / 362 (2.21%)	3 / 365 (0.82%)	
occurrences (all)	8	3	
Nervous system disorders			
Dizziness			
subjects affected / exposed	10 / 362 (2.76%)	4 / 365 (1.10%)	
occurrences (all)	11	4	
Headache			
subjects affected / exposed	47 / 362 (12.98%)	24 / 365 (6.58%)	
occurrences (all)	57	26	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	10 / 362 (2.76%)	5 / 365 (1.37%)	
occurrences (all)	13	5	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	8 / 362 (2.21%)	8 / 365 (2.19%)	
occurrences (all)	9	10	
Nausea			
subjects affected / exposed	70 / 362 (19.34%)	8 / 365 (2.19%)	
occurrences (all)	79	12	
Vomiting			
subjects affected / exposed	11 / 362 (3.04%)	6 / 365 (1.64%)	
occurrences (all)	12	6	
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	8 / 362 (2.21%)	1 / 365 (0.27%)	
occurrences (all)	8	1	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	46 / 362 (12.71%)	10 / 365 (2.74%)	
occurrences (all)	51	11	
Dermatitis atopic			
subjects affected / exposed	17 / 362 (4.70%)	13 / 365 (3.56%)	
occurrences (all)	20	14	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	2 / 362 (0.55%)	8 / 365 (2.19%)	
occurrences (all)	2	8	
Infections and infestations			
COVID-19			
subjects affected / exposed	14 / 362 (3.87%)	12 / 365 (3.29%)	
occurrences (all)	14	12	
Conjunctivitis			
subjects affected / exposed	8 / 362 (2.21%)	35 / 365 (9.59%)	
occurrences (all)	8	41	
Herpes simplex			
subjects affected / exposed	12 / 362 (3.31%)	5 / 365 (1.37%)	
occurrences (all)	13	5	
Folliculitis			
subjects affected / exposed	12 / 362 (3.31%)	3 / 365 (0.82%)	
occurrences (all)	13	3	
Nasopharyngitis			
subjects affected / exposed	14 / 362 (3.87%)	12 / 365 (3.29%)	
occurrences (all)	15	12	
Herpes zoster			
subjects affected / exposed	9 / 362 (2.49%)	2 / 365 (0.55%)	
occurrences (all)	9	2	
Oral herpes			
subjects affected / exposed	9 / 362 (2.49%)	15 / 365 (4.11%)	
occurrences (all)	9	20	
Upper respiratory tract infection			
subjects affected / exposed	10 / 362 (2.76%)	9 / 365 (2.47%)	
occurrences (all)	11	9	
Urinary tract infection			
subjects affected / exposed	8 / 362 (2.21%)	7 / 365 (1.92%)	
occurrences (all)	9	7	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 July 2020	Amendment 1: Country specific changes for Czech republic Section 5.2: Subjects with increased risk of developing venous thromboembolism were excluded. Section 6.5.2.: If a subject required high potency topical therapy or systemic rescue therapy, they were to be permanently discontinued from the study intervention, have an End of Treatment visit and enter the 4-week follow-up period.
14 August 2020	Amendment 2: Per updated safety information, subjects with increased risk of developing venous thromboembolism were excluded. Inclusion criterion updated to require a clinical diagnosis of AD at least 6 months prior to Day 1 instead of at least 1 year. Exclusion of prior use of dupilumab has been expanded to include all IL-4 and IL-13 antagonists. Healthcare Resource Utilization (HCRU) assessment was moved from Week 16 to Week 12. Requirements for mental health professional assessments and recurrent suicidal ideation and behavior were clarified. Data collection requirements for adverse events of conjunctivitis were added. Temporary discontinuation timeframe updated for the injectable study intervention and requirement added for subjects who need systemic rescue therapy to temporarily discontinue study intervention while taking systemic rescue therapy. Added isoniazid as a prohibited concomitant medication.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported