



Clinical trial results:

A Randomized, Open-Label, Parallel-Group Study to Evaluate the Safety and Efficacy of Abrocitinib 100 mg and 200 mg Tablets in Participants Aged 12 Years and Older with Moderate to Severe Atopic Dermatitis in India

Summary

EudraCT number	2024-000141-26
Trial protocol	Outside EU/EEA
Global end of trial date	14 March 2024

Results information

Result version number	v1 (current)
This version publication date	30 August 2024
First version publication date	30 August 2024

Trial information

Trial identification

Sponsor protocol code	B7451094
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05375929
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235E42nd Street, New York, United States, NY 10017
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	09 July 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Main study: To evaluate the safety of abrocitinib in participants aged 12 years and older with moderate to severe atopic dermatitis (AD). Substudy: To evaluate the potential effects of abrocitinib on bone development in adolescent participants 12 to less than (<) 18 years of age, as assessed by knee magnetic resonance imaging (MRI).

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 Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 July 2022
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	India: 200
Worldwide total number of subjects	200
EEA total number of subjects	0

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)	33
Adults (18-64 years)	156
From 65 to 84 years	11
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 200 participants aged greater than or equal to ($\geq$) 12 years with moderate to severe atopic dermatitis (AD) were enrolled in the study. As per statistical analysis plan (SAP) participants' disposition, and discontinuation were to be summarized by treatment arm.

Pre-assignment

Screening details:

Study had main study and substudy. Adolescent participants consented for substudy at main study inform consent/assent to receive study intervention assigned in the main study after the 12-week treatment period, until 1 year after randomization in the main study or until they turned 18.

Period 1

Period 1 title	Overall Study: Treatment
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Main Study: Abrocitinib 200 mg QD

Arm description:

Participants received abrocitinib 200 milligram (mg), orally once daily (QD) for 12 weeks.

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

Dosage and administration details:

Participants received abrocitinib 200 mg, orally QD for 12 weeks.

Arm title	Main Study: Abrocitinib 100 mg QD
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Arm description:

Participants received abrocitinib 100 mg, orally QD for 12 weeks.

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

Dosage and administration details:

Participants received abrocitinib 100 mg, orally QD for 12 weeks.

Arm title	Substudy: Abrocitinib 200 mg
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Arm description:

Eligible adolescent participants who received abrocitinib 200 mg orally QD for 12 weeks in main study, continued to receive the same treatment in similar way until 1 year after randomization (on Day 1) from main study.

Arm type	Experimental
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Investigational medicinal product name	Abrocitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received abrocitinib 200 mg, orally QD for 1 year after randomization.	
Arm title	Substudy: Abrocitinib 100 mg

Arm description:

Eligible adolescent participants who received abrocitinib 100 mg orally QD for 12 weeks in main study, continued to receive the same treatment in similar way until 1 year after randomization (on Day 1) from main study.

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

Dosage and administration details:

Participants received abrocitinib 100 mg, orally QD for 1 year after randomization.

Number of subjects in period 1	Main Study: Abrocitinib 200 mg QD	Main Study: Abrocitinib 100 mg QD	Substudy: Abrocitinib 200 mg
Started	99	101	19
Completed	91	94	12
Not completed	8	7	7
Consent withdrawn by subject	6	5	-
Physician decision	-	-	4
Adverse event, non-fatal	1	-	2
Lost to follow-up	1	1	1
Withdrawal by parent/guardian	-	1	-

Number of subjects in period 1	Substudy: Abrocitinib 100 mg
Started	16
Completed	15
Not completed	1
Consent withdrawn by subject	-
Physician decision	-
Adverse event, non-fatal	-
Lost to follow-up	-
Withdrawal by parent/guardian	1

Period 2	
Period 2 title	Overall Study: Follow-up
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded
Arms	
Are arms mutually exclusive?	No
Arm title	Main Study: Abrocitinib 200 mg QD
Arm description:	
Participants received abrocitinib 200 mg, orally QD for 12 weeks.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Main Study: Abrocitinib 100 mg QD
Arm description:	
Participants received abrocitinib 100 mg, orally QD for 12 weeks.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Substudy: Abrocitinib 200 mg
Arm description:	
Eligible adolescent participants who received abrocitinib 200 mg orally QD for 12 weeks in main study, continued to receive the same treatment in similar way until 1 year after randomization (on Day 1) from main study.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Substudy: Abrocitinib 100 mg
Arm description:	
Eligible adolescent participants who received abrocitinib 100 mg orally QD for 12 weeks in main study, continued to receive the same treatment in similar way until 1 year after randomization (on Day 1) from main study.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2	Main Study: Abrocitinib 200 mg QD	Main Study: Abrocitinib 100 mg QD	Substudy: Abrocitinib 200 mg
Started	91	94	12
Completed	90	93	17
Not completed	1	1	0
Did not complete study follow-up	-	1	-
Lost to follow-up	1	-	-
Joined	0	0	5
Follow-up	-	-	5

Number of subjects in period 2	Substudy: Abrocitinib 100 mg
Started	15
Completed	15
Not completed	0
Did not complete study follow-up	-
Lost to follow-up	-
Joined	0
Follow-up	-

Baseline characteristics

Reporting groups

Reporting group title	Main Study: Abrocitinib 200 mg QD
Reporting group description:	
Participants received abrocitinib 200 milligram (mg), orally once daily (QD) for 12 weeks.	
Reporting group title	Main Study: Abrocitinib 100 mg QD
Reporting group description:	
Participants received abrocitinib 100 mg, orally QD for 12 weeks.	
Reporting group title	Substudy: Abrocitinib 200 mg
Reporting group description:	
Eligible adolescent participants who received abrocitinib 200 mg orally QD for 12 weeks in main study, continued to receive the same treatment in similar way until 1 year after randomization (on Day 1) from main study.	
Reporting group title	Substudy: Abrocitinib 100 mg
Reporting group description:	
Eligible adolescent participants who received abrocitinib 100 mg orally QD for 12 weeks in main study, continued to receive the same treatment in similar way until 1 year after randomization (on Day 1) from main study.	

Reporting group values	Main Study: Abrocitinib 200 mg QD	Main Study: Abrocitinib 100 mg QD	Substudy: Abrocitinib 200 mg
Number of subjects	99	101	19
Age categorical			
Units: Participants			
Adolescents (12-17 years)	17	16	17
Adults (18-64 years)	78	78	2
From 65-84 years	4	7	0
Age Continuous			
Units: Years			
arithmetic mean	35.37	37.50	14.79
standard deviation	± 17.19	± 17.49	± 2.25
Sex: Female, Male			
Units: Participants			
Female	61	48	12
Male	38	53	7
Race			
Units: Subjects			
Asian	99	101	19
Ethnicity			
Units: Subjects			
Not Hispanic or Latino	99	101	19

Reporting group values	Substudy: Abrocitinib 100 mg	Total	
Number of subjects	16	200	
Age categorical			
Units: Participants			
Adolescents (12-17 years)	16	33	
Adults (18-64 years)	0	156	

From 65-84 years	0	11	
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Age Continuous Units: Years arithmetic mean standard deviation	14.44 ± 1.36	-	
Sex: Female, Male Units: Participants			
Female	7	109	
Male	9	91	
Race Units: Subjects			
Asian	16	200	
Ethnicity Units: Subjects			
Not Hispanic or Latino	16	200	

End points

End points reporting groups

Reporting group title	Main Study: Abrocitinib 200 mg QD
Reporting group description: Participants received abrocitinib 200 milligram (mg), orally once daily (QD) for 12 weeks.	
Reporting group title	Main Study: Abrocitinib 100 mg QD
Reporting group description: Participants received abrocitinib 100 mg, orally QD for 12 weeks.	
Reporting group title	Substudy: Abrocitinib 200 mg
Reporting group description: Eligible adolescent participants who received abrocitinib 200 mg orally QD for 12 weeks in main study, continued to receive the same treatment in similar way until 1 year after randomization (on Day 1) from main study.	
Reporting group title	Substudy: Abrocitinib 100 mg
Reporting group description: Eligible adolescent participants who received abrocitinib 100 mg orally QD for 12 weeks in main study, continued to receive the same treatment in similar way until 1 year after randomization (on Day 1) from main study.	
Reporting group title	Main Study: Abrocitinib 200 mg QD
Reporting group description: Participants received abrocitinib 200 mg, orally QD for 12 weeks.	
Reporting group title	Main Study: Abrocitinib 100 mg QD
Reporting group description: Participants received abrocitinib 100 mg, orally QD for 12 weeks.	
Reporting group title	Substudy: Abrocitinib 200 mg
Reporting group description: Eligible adolescent participants who received abrocitinib 200 mg orally QD for 12 weeks in main study, continued to receive the same treatment in similar way until 1 year after randomization (on Day 1) from main study.	
Reporting group title	Substudy: Abrocitinib 100 mg
Reporting group description: Eligible adolescent participants who received abrocitinib 100 mg orally QD for 12 weeks in main study, continued to receive the same treatment in similar way until 1 year after randomization (on Day 1) from main study.	
Subject analysis set title	Main Study: Abrocitinib 200 mg
Subject analysis set type	Safety analysis
Subject analysis set description: Participants included in this analysis set are those who actually received abrocitinib 200 mg, orally QD for 12 weeks.	
Subject analysis set title	Main Study: Abrocitinib 100 mg
Subject analysis set type	Safety analysis
Subject analysis set description: Participants included in this analysis set are those who actually received abrocitinib 100 mg, orally QD for 12 weeks.	
Subject analysis set title	Main Study: Abrocitinib 200 mg
Subject analysis set type	Full analysis
Subject analysis set description: Participants included in this analysis set are according to their randomization in abrocitinib 200 mg group.	
Subject analysis set title	Main Study: Abrocitinib 100 mg
Subject analysis set type	Full analysis
Subject analysis set description: Participants included in this analysis set are according to their randomization in abrocitinib 100 mg	

Primary: Number of Participants With Adverse Events (AEs) and Serious AEs (SAEs): Main Study

End point title	Number of Participants With Adverse Events (AEs) and Serious AEs (SAEs): Main Study ^[1]
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End point description:

An AE was any untoward medical occurrence in a participant or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly; was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic or other situations where medical or scientific judgement should be exercised by investigator. AEs included SAEs and all non-SAEs. Safety analysis set included all participants randomly assigned to study intervention and who had taken at least 1 dose of study intervention. Participants were analyzed according to the treatment they actually received.

End point type	Primary
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End point timeframe:

From Day 1 of dosing up to 4 weeks post last dose (maximum up to Week 16)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

End point values	Main Study: Abrocitinib 200 mg	Main Study: Abrocitinib 100 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	99	101		
Units: Count of Participants				
AEs	30	26		
SAEs	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Eczema Area and Severity Index (EASI) Response $\geq$ 75% Improvement From Baseline at Week 12: Main Study

End point title	Percentage of Participants Achieving Eczema Area and Severity Index (EASI) Response $\geq$ 75% Improvement From Baseline at Week 12: Main Study
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End point description:

EASI evaluated severity of participant's AD based on both severity of lesion clinical signs and % of body surface area (BSA) affected. Severity of clinical signs of AD (erythema [E], induration/papulation [I], excoriation [Ex] and lichenification [L]) scored separately for each of 4 body regions (head and neck [h], upper limbs [u], trunk [t]-[including axillae and groin] and lower limbs [l]-[including buttocks]) on 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score was based upon % 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 = $0.1 \times Ah \times (Eh + Ih + Exh + Lh) + 0.2 \times Au \times (Eu + Iu + Exu + Lu) + 0.3 \times At \times (Et + It + Ext + Lt) + 0.4 \times Al \times (El + Il + Exl + Ll)$; A = EASI area score. EASI score range: 0.0 to 72.0, higher scores = greater severity. Full analysis analyzed. NRI applied. Number of Participants Analyzed = participants evaluable.

End point type	Secondary
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End point timeframe:

Baseline (prior to dosing on Day 1), Week 12

End point values	Main Study: Abrocitinib 200 mg	Main Study: Abrocitinib 100 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	99	100		
Units: Percentage of participants				
number (confidence interval 95%)	71.7 (62.8 to 80.6)	69.0 (59.9 to 78.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved Investigator's Global Assessment (IGA) Score of Clear (0) or Almost Clear (1) and ≥ 2 Points Improvement From Baseline at Week 12: Main Study

End point title	Percentage of Participants Who Achieved Investigator's Global Assessment (IGA) Score of Clear (0) or Almost Clear (1) and ≥ 2 Points Improvement From Baseline at Week 12: Main Study
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End point description:

IGA assesses severity of AD on 5-point scale. Scores: 0= clear (no AD inflammatory signs except for any residual discolouration [post-inflammatory hyperpigmentation and/or hypopigmentation]); 1= almost clear (AD not entirely cleared- light pink residual lesions [except post-inflammatory hyperpigmentation], just barely 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). Full analysis set analyzed. Non-responder imputation (NRI) applied. Number of Participants Analyzed = participants evaluable.

End point type	Secondary
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End point timeframe:

Baseline (prior to dosing on Day 1), Week 12

End point values	Main Study: Abrocitinib 200 mg	Main Study: Abrocitinib 100 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	99	100		
Units: Percentage of participants				
number (confidence interval 95%)	48.5 (38.6 to 58.3)	50.0 (40.2 to 59.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient-Oriented Eczema Measure (POEM) Score at Weeks 2, 4, 8 and 12: Main Study

End point title	Change From Baseline in Patient-Oriented Eczema Measure (POEM) Score at Weeks 2, 4, 8 and 12: Main Study
End point description: POEM is a 7-item participant reported outcome (PRO) measure to assess the impact of AD over the past week. Items were: dryness or roughness of skin in day, skin being itchy in day, skin flaking off in day, skin cracking in day, skin bleeding in day, skin weeping or oozing in day and sleep disturbed in night. Each item is scored from 0 to 4, depending on number of days/night (for sleep items) over the past week symptoms happened, where 0= no days, 1= "1-2 days", 2= "3-4 days", 3= "5-6 days" and 4= "every day". Scores from all items are added up, which results in POEM score, ranging from 0 to 28, higher scores = greater severity and greater symptom burden. FAS evaluated. Participants were analyzed according to the treatment arm they were randomized to. All participants reported under Number of Participants Analyzed contributed data to the table but may not have evaluable data for every row.	
End point type	Secondary
End point timeframe: Baseline (prior to dosing on Day 1), Weeks 2, 4, 8 and 12	

End point values	Main Study: Abrocitinib 200 mg	Main Study: Abrocitinib 100 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	100	100		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 2 (97, 98)	-6.3 (± 4.97)	-5.1 (± 5.12)		
Week 4 (96, 96)	-9.4 (± 5.42)	-8.1 (± 5.49)		
Week 8 (94, 96)	-12.0 (± 5.98)	-10.3 (± 5.55)		
Week 12 (92, 93)	-14.2 (± 5.88)	-12.4 (± 6.02)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Scoring Atopic Dermatitis (SCORAD) Response ≥ 75% Improvement From Baseline at Week 12: Main Study

End point title	Percentage of Participants Achieving Scoring Atopic Dermatitis (SCORAD) Response ≥ 75% Improvement From Baseline at Week 12: Main Study
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End point description:

SCORAD: scoring index for AD combining extent (A), severity (B), subjective symptoms (C). A: rule of 9 was used to calculate BSA affected by AD as a % of whole BSA for each body region- head and neck 9%; upper limbs 9% each; lower limbs 18% each; anterior trunk 18%; back 18%; 1% for genitals. Score for each body region was added to determine A (0-100). B: severity of each sign (erythema; edema; oozing; excoriation; lichenification; dryness) assessed as none =0, mild =1, moderate =2, severe =3. Severity scores were added to give B (0-18). C: pruritus and sleep, each was scored by participant/caregiver using visual analogue scale (VAS) where 0= no itch/no sleeplessness and 10= worst imaginable itch/sleeplessness. Scores for itch and sleeplessness were added to give C (0-20). Total SCORAD was calculated: $A/5 + 7*B/2 + C$; SCORAD range from 0-103; higher SCORAD scores = greater severity. Full analysis analyzed. NRI applied. Number of Participants Analyzed = participants evaluable.

End point type	Secondary
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End point timeframe:

Baseline (prior to dosing on Day 1), Week 12

End point values	Main Study: Abrocitinib 200 mg	Main Study: Abrocitinib 100 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	99	100		
Units: Percentage of participants				
number (confidence interval 95%)	47.5 (37.6 to 57.3)	43.0 (33.3 to 52.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Atopic Dermatitis Control Tool (ADCT) Score at Weeks 2, 4, 8 and 12: Main Study

End point title	Change From Baseline in Atopic Dermatitis Control Tool (ADCT) Score at Weeks 2, 4, 8 and 12: Main Study
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End point description:

ADCT score is used to measure the participants perceived AD control. It consists of 6 questions (overall severity of symptoms, days with intense episodes of itching, intensity of bother, problem with sleep, impact on daily activities, and impact on mood or emotions) which are evaluated over the past week on scale from 0 to 4. Scores from all 6 questions are added up to provide ADCT score, ranging from 0 to 24, where higher scores indicate lower AD control. FAS included all participants randomly assigned to study intervention and had taken at least 1 dose of study intervention. Participants were analyzed according to the treatment arm they were randomized to. All participants reported under Number of Participants Analyzed contributed data to the table but may not have evaluable data for every row.

End point type	Secondary
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End point timeframe:

Baseline (prior to dosing on Day 1), Weeks 2, 4, 8 and 12

End point values	Main Study: Abrocitinib 200 mg	Main Study: Abrocitinib 100 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	100	100		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 2 (97, 98)	-5.2 (± 4.06)	-4.4 (± 4.57)		
Week 4 (96, 96)	-8.1 (± 4.90)	-7.4 (± 4.64)		
Week 8 (94, 96)	-10.7 (± 4.80)	-9.4 (± 5.21)		
Week 12 (91, 93)	-12.8 (± 5.33)	-11.5 (± 5.64)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Bone Safety Findings in Knee Magnetic Resonance Imaging (MRI) at 1 Year After Randomization: Substudy

End point title	Percentage of Participants With Bone Safety Findings in Knee Magnetic Resonance Imaging (MRI) at 1 Year After Randomization: Substudy ^[2]
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End point description:

MRI imaging session was performed when participant was in supine position in the confined space of the MRI scanner for approximately 30 mins. The assessments included evaluation of epiphyseal plate closure and mineralization of cartilage at the growth centres. Substudy analysis set included all participants who entered the substudy and who took at least 1 dose of study intervention during the substudy.

End point type	Secondary
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End point timeframe:

Up to 1 year from randomization on Day 1 of main study

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Substudy: Abrocitinib 200 mg	Substudy: Abrocitinib 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	16		
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 17.6)	0 (0.0 to 20.6)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Main Study: From Day 1 of dosing up to 4 weeks post last dose (last dose at Week 12, maximum follow-up till Week 16); Sub Study: From Day 1 of dosing (in main study) up to 4 weeks post last dose (last dose at Year 1, maximum follow-up till Year 1.08)

Adverse event reporting additional description:

Same event may appear as both AE and SAE but are distinct events. An event may be categorized as serious in 1 participant and non-serious in another, or a participant may have experienced both SAE and non-SAE. MedDRA used: for main study v 26.0; for substudy v 27.0. Safety analysis set used for main study; substudy analysis set used for substudy.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0, 27.0

Reporting groups

Reporting group title	Abrocitinib 200 mg QD
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Reporting group description:

Enter Description here

Reporting group title	Substudy: Abrocitinib 200 mg
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Reporting group description:

Eligible adolescent participants who received abrocitinib 200 mg orally QD for 12 weeks in main study, continued to receive the same treatment in similar way until 1 year after randomization (on Day 1) from main study.

Reporting group title	Substudy: Abrocitinib 100 mg
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Reporting group description:

Eligible adolescent participants who received abrocitinib 100 mg orally QD for 12 weeks in main study, continued to receive the same treatment in similar way until 1 year after randomization (on Day 1) from main study.

Reporting group title	Abrocitinib 100 mg QD
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Reporting group description:

Enter Description here

Serious adverse events	Abrocitinib 200 mg QD	Substudy: Abrocitinib 200 mg	Substudy: Abrocitinib 100 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99 (0.00%)	0 / 19 (0.00%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Radius fracture			
subjects affected / exposed	0 / 99 (0.00%)	0 / 19 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Abrocitinib 100 mg QD		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 101 (0.99%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Radius fracture			
subjects affected / exposed	1 / 101 (0.99%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Abrocitinib 200 mg QD	Substudy: Abrocitinib 200 mg	Substudy: Abrocitinib 100 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 99 (22.22%)	8 / 19 (42.11%)	5 / 16 (31.25%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 99 (1.01%)	0 / 19 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 99 (0.00%)	0 / 19 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 99 (0.00%)	0 / 19 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 99 (0.00%)	1 / 19 (5.26%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 99 (1.01%)	1 / 19 (5.26%)	2 / 16 (12.50%)
occurrences (all)	1	1	4
Gastrointestinal disorders			

Vomiting subjects affected / exposed occurrences (all)	3 / 99 (3.03%) 3	0 / 19 (0.00%) 0	0 / 16 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	9 / 99 (9.09%) 9	2 / 19 (10.53%) 2	0 / 16 (0.00%) 0
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	4 / 99 (4.04%) 6	0 / 19 (0.00%) 0	0 / 16 (0.00%) 0
Gastritis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 19 (0.00%) 0	1 / 16 (6.25%) 1
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1	1 / 19 (5.26%) 1	1 / 16 (6.25%) 1
Asthma subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 19 (0.00%) 0	1 / 16 (6.25%) 1
Skin and subcutaneous tissue disorders			
Dermatitis atopic subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1	1 / 19 (5.26%) 1	2 / 16 (12.50%) 2
Rosacea subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	1 / 19 (5.26%) 1	0 / 16 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	4 / 99 (4.04%) 4	0 / 19 (0.00%) 0	0 / 16 (0.00%) 0
Infections and infestations			
Eczema herpeticum subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	1 / 19 (5.26%) 2	0 / 16 (0.00%) 0
Herpes zoster subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	1 / 19 (5.26%) 1	0 / 16 (0.00%) 0

Joint tuberculosis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	1 / 19 (5.26%) 1	0 / 16 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	2 / 19 (10.53%) 2	1 / 16 (6.25%) 1
Pharyngitis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 19 (0.00%) 0	1 / 16 (6.25%) 1
Pyoderma subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 19 (0.00%) 0	1 / 16 (6.25%) 1
Varicella subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	1 / 19 (5.26%) 1	0 / 16 (0.00%) 0
Varicella zoster virus infection subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	1 / 19 (5.26%) 1	0 / 16 (0.00%) 0
Viral infection subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 19 (0.00%) 0	1 / 16 (6.25%) 1

Non-serious adverse events	Abrocitinib 100 mg QD		
Total subjects affected by non-serious adverse events subjects affected / exposed	20 / 101 (19.80%)		
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all)	3 / 101 (2.97%) 3		
Vascular disorders Hypotension subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0		
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0		

Headache subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0		
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	3 / 101 (2.97%) 3		
Gastrointestinal disorders Vomiting subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Gastrooesophageal reflux disease subjects affected / exposed occurrences (all) Gastritis subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0 5 / 101 (4.95%) 5 2 / 101 (1.98%) 2 0 / 101 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Asthma subjects affected / exposed occurrences (all)	3 / 101 (2.97%) 3 0 / 101 (0.00%) 0		
Skin and subcutaneous tissue disorders Dermatitis atopic subjects affected / exposed occurrences (all) Rosacea subjects affected / exposed occurrences (all) Pruritus	4 / 101 (3.96%) 4 0 / 101 (0.00%) 0		

subjects affected / exposed	2 / 101 (1.98%)		
occurrences (all)	3		
Infections and infestations			
Eczema herpeticum			
subjects affected / exposed	0 / 101 (0.00%)		
occurrences (all)	0		
Herpes zoster			
subjects affected / exposed	0 / 101 (0.00%)		
occurrences (all)	0		
Joint tuberculosis			
subjects affected / exposed	0 / 101 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 101 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	0 / 101 (0.00%)		
occurrences (all)	0		
Pyoderma			
subjects affected / exposed	0 / 101 (0.00%)		
occurrences (all)	0		
Varicella			
subjects affected / exposed	0 / 101 (0.00%)		
occurrences (all)	0		
Varicella zoster virus infection			
subjects affected / exposed	0 / 101 (0.00%)		
occurrences (all)	0		
Viral infection			
subjects affected / exposed	0 / 101 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 March 2022	Added SCORAD efficacy assessment for atopic dermatitis as a secondary endpoint. Added laboratory tests at end of treatment (EoT) visit of the substudy. Updated substudy schedule of assessments (SoA) and relevant sections.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

One participant was randomized to abrocitinib 200 mg arm but received abrocitinib 100 mg, hence for safety analysis set of main study that participant was included in 100 mg arm and for full analysis set that participant was included in 200 mg arm.

Notes: