



Clinical trial results:

A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study of the Efficacy and Safety of INCB054707 in Participants With Prurigo Nodularis

Summary

EudraCT number	2021-006329-23
Trial protocol	ES
Global end of trial date	28 February 2024

Results information

Result version number	v1 (current)
This version publication date	20 February 2025
First version publication date	20 February 2025

Trial information

Trial identification

Sponsor protocol code	INCB 54707-206
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Incyte Corporation
Sponsor organisation address	1801 Augustine Cutoff Drive, Wilmington, United States, 19803
Public contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.com
Scientific contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.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	28 February 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	28 February 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study was to evaluate the efficacy and safety of povorcitinib in participants with prurigo nodularis over a 16-week double-blind, placebo-controlled treatment period, followed by a 24-week, single-blind extension period.

Protection of trial subjects:

This study was performed in accordance with ethical principles that have their origin in the Declaration of Helsinki and was conducted in adherence to the study Protocol, applicable Good Clinical Practices, and applicable laws and country-specific regulations in which the study was conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 November 2021
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	Canada: 15
Country: Number of subjects enrolled	Germany: 31
Country: Number of subjects enrolled	Spain: 13
Country: Number of subjects enrolled	Poland: 11
Country: Number of subjects enrolled	Puerto Rico: 1
Country: Number of subjects enrolled	United States: 75
Worldwide total number of subjects	146
EEA total number of subjects	55

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)	108
From 65 to 84 years	38
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study was conducted across 40 sites in Canada, Germany, Spain, Poland, Puerto Rico, and the United States.

Period 1

Period 1 title	16-week Placebo-controlled (PC) Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

On Day 1, participants were randomized to receive matching placebo once daily (QD) and stratified by Investigator's Global Assessment (IGA) score (3 versus 4). Participants received blinded study drug through Week 16.

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

Dosage and administration details:

Matching placebo tablets administered orally once daily

Arm title	Povorcitinib 15 mg
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Arm description:

On Day 1, participants were randomized to receive povorcitinib 15 milligrams (mg) QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16.

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

Dosage and administration details:

15 mg tablets administered orally once daily

Arm title	Povorcitinib 45 mg
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Arm description:

On Day 1, participants were randomized to receive povorcitinib 45 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16.

Arm type	Experimental
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Investigational medicinal product name	povorcitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
15 mg tablets administered orally once daily	
Arm title	Povorcitinib 75 mg

Arm description:

On Day 1, participants were randomized to receive povorcitinib 75 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16.

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

Dosage and administration details:

15 mg tablets administered orally once daily

Number of subjects in period 1	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg
Started	37	36	36
Completed	32	29	31
Not completed	5	7	5
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	2	4	2
Adverse event, non-fatal	1	1	1
Sponsor Decision	-	-	-
Lost to follow-up	-	-	1
Lack of efficacy	1	-	-
Protocol deviation	1	1	1

Number of subjects in period 1	Povorcitinib 75 mg
Started	37
Completed	33
Not completed	4
Adverse event, serious fatal	-
Consent withdrawn by subject	2
Adverse event, non-fatal	-
Sponsor Decision	1
Lost to follow-up	-
Lack of efficacy	-
Protocol deviation	1

Period 2

Period 2 title	24-week Extension Period
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo to povorcitinib 45 mg

Arm description:

Participants who received placebo during the 16-week placebo-controlled period and were classified as responders at Week 16 received povorcitinib 45 mg QD for 24 weeks in the extension period. Responders were defined as participants who had a ≥ 4 -point decrease in Itch Numerical Rating Scale (NRS) score and Investigator's Global Assessment-Treatment Success (IGA-TS) who did not receive rescue therapy during the placebo-controlled period.

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

Dosage and administration details:

15 mg tablets administered orally once daily

Arm title	Povorcitinib 15 mg to 45 mg
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Arm description:

Participants who received povorcitinib 15 mg during the 16-week placebo-controlled period and were classified as responders at Week 16 received povorcitinib 45 mg QD for 24 weeks in the extension period. Responders were defined as participants who had a ≥ 4 -point decrease in Itch NRS score and IGA-TS who did not receive rescue therapy during the placebo-controlled period.

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

Dosage and administration details:

15 mg tablets administered orally once daily

Arm title	Povorcitinib 45 mg
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Arm description:

Participants who received povorcitinib 45 mg during the 16-week placebo-controlled period and were classified as responders at Week 16 received povorcitinib 45 mg QD for an additional 24 weeks in the extension period. Responders were defined as participants who had a ≥ 4 -point decrease in Itch NRS

score and IGA-TS who did not receive rescue therapy during the placebo-controlled period.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
15 mg tablets administered orally once daily	
Arm title	Povorcitinib 75 mg to 45 mg

Arm description:

Participants who received povorcitinib 75 mg during the 16-week placebo-controlled period and were classified as responders at Week 16 received povorcitinib 45 mg QD for 24 weeks in the extension period. Responders were defined as participants who had a ≥ 4 -point decrease in Itch NRS score and IGA-TS who did not receive rescue therapy during the placebo-controlled period.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
15 mg tablets administered orally once daily	
Arm title	Placebo to povorcitinib 75 mg

Arm description:

Participants who received placebo during the 16-week placebo-controlled period and were classified as non-responders at Week 16 received povorcitinib 75 mg QD for 24 weeks in the extension period. Non-responders were defined as participants not meeting the definition of a responder.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
15 mg tablets administered orally once daily	
Arm title	Povorcitinib 15 mg to 75 mg

Arm description:

Participants who received povorcitinib 15 mg during the 16-week placebo-controlled period and were classified as non-responders at Week 16 received povorcitinib 75 mg QD for 24 weeks in the extension period. Non-responders were defined as participants not meeting the definition of a responder.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
15 mg tablets administered orally once daily	
Arm title	Povorcitinib 45 mg to 75 mg

Arm description:

Participants who received povorcitinib 45 mg during the 16-week placebo-controlled period and were classified as non-responders at Week 16 received povorcitinib 75 mg QD for 24 weeks in the extension

period. Non-responders were defined as participants not meeting the definition of a responder.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
15 mg tablets administered orally once daily	
Arm title	Povorcitinib 75 mg

Arm description:

Participants who received povorcitinib 75 mg during the 16-week placebo-controlled period and were classified as non-responders at Week 16 received povorcitinib 75 mg QD for an additional 24 weeks in the extension period. Non-responders were defined as participants not meeting the definition of a responder.

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

Dosage and administration details:

15 mg tablets administered orally once daily

Number of subjects in period 2^[1]	Placebo to povorcitinib 45 mg	Povorcitinib 15 mg to 45 mg	Povorcitinib 45 mg
Started	1	4	8
Completed	1	4	7
Not completed	0	0	1
Site Closure	-	-	-
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	-
Sponsor Decision	-	-	-
Lost to follow-up	-	-	1
Lack of efficacy	-	-	-

Number of subjects in period 2^[1]	Povorcitinib 75 mg to 45 mg	Placebo to povorcitinib 75 mg	Povorcitinib 15 mg to 75 mg
Started	15	30	25
Completed	12	25	22
Not completed	3	5	3
Site Closure	-	1	-
Consent withdrawn by subject	-	1	2
Adverse event, non-fatal	2	2	-
Sponsor Decision	1	-	-

Lost to follow-up	-	1	1
Lack of efficacy	-	-	-

Number of subjects in period 2^[1]	Povorcitinib 45 mg to 75 mg	Povorcitinib 75 mg
Started	23	18
Completed	18	13
Not completed	5	5
Site Closure	-	1
Consent withdrawn by subject	2	1
Adverse event, non-fatal	1	3
Sponsor Decision	-	-
Lost to follow-up	-	-
Lack of efficacy	2	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all participants who completed the Placebo-controlled Period started the Extension Period.

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description:	
On Day 1, participants were randomized to receive matching placebo once daily (QD) and stratified by Investigator's Global Assessment (IGA) score (3 versus 4). Participants received blinded study drug through Week 16.	
Reporting group title	Povorcitinib 15 mg
Reporting group description:	
On Day 1, participants were randomized to receive povorcitinib 15 milligrams (mg) QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16.	
Reporting group title	Povorcitinib 45 mg
Reporting group description:	
On Day 1, participants were randomized to receive povorcitinib 45 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16.	
Reporting group title	Povorcitinib 75 mg
Reporting group description:	
On Day 1, participants were randomized to receive povorcitinib 75 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16.	

Reporting group values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg
Number of subjects	37	36	36
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)	29	27	23
From 65-84 years	8	9	13
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	52.9	56.0	55.6
standard deviation	± 12.32	± 12.92	± 15.25
Sex: Female, Male			
Units: participants			
Female	22	24	27
Male	15	12	9
Race/Ethnicity, Customized			
Units: Subjects			
White/Caucasian	33	31	27
Black/African-American	3	3	5
Asian	0	2	4
American-Indian/Alaska Native	0	0	0
Unknown	1	0	0

Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	7	3	3
Not Hispanic or Latino	30	32	33
Unknown or Not Reported	0	1	0

Reporting group values	Povorcitinib 75 mg	Total	
Number of subjects	37	146	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	29	108	
From 65-84 years	8	38	
85 years and over	0	0	
Age Continuous			
Units: years			
arithmetic mean	55.9		
standard deviation	± 10.18	-	
Sex: Female, Male			
Units: participants			
Female	23	96	
Male	14	50	
Race/Ethnicity, Customized			
Units: Subjects			
White/Caucasian	30	121	
Black/African-American	5	16	
Asian	1	7	
American-Indian/Alaska Native	1	1	
Unknown	0	1	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	3	16	
Not Hispanic or Latino	33	128	
Unknown or Not Reported	1	2	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: On Day 1, participants were randomized to receive matching placebo once daily (QD) and stratified by Investigator's Global Assessment (IGA) score (3 versus 4). Participants received blinded study drug through Week 16.	
Reporting group title	Povorcitinib 15 mg
Reporting group description: On Day 1, participants were randomized to receive povorcitinib 15 milligrams (mg) QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16.	
Reporting group title	Povorcitinib 45 mg
Reporting group description: On Day 1, participants were randomized to receive povorcitinib 45 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16.	
Reporting group title	Povorcitinib 75 mg
Reporting group description: On Day 1, participants were randomized to receive povorcitinib 75 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16.	
Reporting group title	Placebo to povorcitinib 45 mg
Reporting group description: Participants who received placebo during the 16-week placebo-controlled period and were classified as responders at Week 16 received povorcitinib 45 mg QD for 24 weeks in the extension period. Responders were defined as participants who had a ≥ 4 -point decrease in Itch Numerical Rating Scale (NRS) score and Investigator's Global Assessment-Treatment Success (IGA-TS) who did not receive rescue therapy during the placebo-controlled period.	
Reporting group title	Povorcitinib 15 mg to 45 mg
Reporting group description: Participants who received povorcitinib 15 mg during the 16-week placebo-controlled period and were classified as responders at Week 16 received povorcitinib 45 mg QD for 24 weeks in the extension period. Responders were defined as participants who had a ≥ 4 -point decrease in Itch NRS score and IGA-TS who did not receive rescue therapy during the placebo-controlled period.	
Reporting group title	Povorcitinib 45 mg
Reporting group description: Participants who received povorcitinib 45 mg during the 16-week placebo-controlled period and were classified as responders at Week 16 received povorcitinib 45 mg QD for an additional 24 weeks in the extension period. Responders were defined as participants who had a ≥ 4 -point decrease in Itch NRS score and IGA-TS who did not receive rescue therapy during the placebo-controlled period.	
Reporting group title	Povorcitinib 75 mg to 45 mg
Reporting group description: Participants who received povorcitinib 75 mg during the 16-week placebo-controlled period and were classified as responders at Week 16 received povorcitinib 45 mg QD for 24 weeks in the extension period. Responders were defined as participants who had a ≥ 4 -point decrease in Itch NRS score and IGA-TS who did not receive rescue therapy during the placebo-controlled period.	
Reporting group title	Placebo to povorcitinib 75 mg
Reporting group description: Participants who received placebo during the 16-week placebo-controlled period and were classified as non-responders at Week 16 received povorcitinib 75 mg QD for 24 weeks in the extension period. Non-responders were defined as participants not meeting the definition of a responder.	
Reporting group title	Povorcitinib 15 mg to 75 mg
Reporting group description: Participants who received povorcitinib 15 mg during the 16-week placebo-controlled period and were classified as non-responders at Week 16 received povorcitinib 75 mg QD for 24 weeks in the extension period. Non-responders were defined as participants not meeting the definition of a responder.	
Reporting group title	Povorcitinib 45 mg to 75 mg

Reporting group description:

Participants who received povorcitinib 45 mg during the 16-week placebo-controlled period and were classified as non-responders at Week 16 received povorcitinib 75 mg QD for 24 weeks in the extension period. Non-responders were defined as participants not meeting the definition of a responder.

Reporting group title	Povorcitinib 75 mg
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Reporting group description:

Participants who received povorcitinib 75 mg during the 16-week placebo-controlled period and were classified as non-responders at Week 16 received povorcitinib 75 mg QD for an additional 24 weeks in the extension period. Non-responders were defined as participants not meeting the definition of a responder.

Primary: Percentage of participants achieving ≥ 4 -point improvement in Itch Numerical Rating Scale (NRS) score at Week 16

End point title	Percentage of participants achieving ≥ 4 -point improvement in Itch Numerical Rating Scale (NRS) score at Week 16
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End point description:

Each evening, the participants assessed their worst level of itch during the past 24 hours on a scale of 0 (no itch) to 10 (worst itch imaginable). The Baseline Itch NRS score was determined by averaging the 7 daily Itch NRS scores before Day 1 (i.e., Day -7 to Day -1). If ≥ 4 of the 7 days of the daily Itch NRS scores were missing prior to Day 1, then the Baseline Itch NRS score was set to "missing." The by-visit Itch NRS score for postbaseline visits was determined by averaging the 7 daily Itch NRS scores before the visit day. If 4 or more daily Itch NRS scores out of the 7 days before the visit day were missing, the Itch NRS score at the visit was set to missing. Analysis was conducted in members of the Intent-to-Treat (ITT) Population, comprised of all randomized participants. Missing post-Baseline values and rescue therapy recipients for all subsequent visits after the initiation date of rescue therapy were imputed as nonresponders.

End point type	Primary
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End point timeframe:

Baseline; Week 16

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[1]	36 ^[2]	36 ^[3]	37 ^[4]
Units: percentage of participants				
number (confidence interval 95%)	8.1 (1.7 to 21.9)	36.1 (20.8 to 53.8)	44.4 (27.9 to 61.9)	56.8 (39.5 to 72.9)

Notes:

[1] - ITT Population. The 95% confidence interval was based on the Clopper-Pearson exact method.

[2] - ITT Population. The 95% confidence interval was based on the Clopper-Pearson exact method.

[3] - ITT Population. The 95% confidence interval was based on the Clopper-Pearson exact method.

[4] - ITT Population. The 95% confidence interval was based on the Clopper-Pearson exact method.

Statistical analyses

Statistical analysis title	Placebo:15 mg; Exact logistic regression
Comparison groups	Placebo v Povorcitinib 15 mg

Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0061 ^[5]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	7.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	45.4

Notes:

[5] - Exact Logistic regression: (response at Week 16 = treatment + stratification factor [Day 1 Investigator's Global Assessment score (3 or 4)])

Statistical analysis title	Placebo:75 mg; Exact logistic regression
Comparison groups	Placebo v Povorcitinib 75 mg
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 ^[6]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	16.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.9
upper limit	107.5

Notes:

[6] - Exact Logistic regression: (response at Week 16 = treatment + stratification factor [Day 1 Investigator's Global Assessment score (3 or 4)])

Statistical analysis title	Placebo:45 mg; Exact logistic regression
Comparison groups	Placebo v Povorcitinib 45 mg
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0005 ^[7]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	10.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.3
upper limit	65.6

Notes:

[7] - Exact Logistic regression: (response at Week 16 = treatment + stratification factor [Day 1 Investigator's Global Assessment score (3 or 4)])

Secondary: Percentage of participants achieving Investigator's Global Assessment-

Treatment Success (IGA-TS) (IGA score of 0 or 1 with a ≥ 2 -grade improvement from Baseline) at Week 16

End point title	Percentage of participants achieving Investigator's Global Assessment-Treatment Success (IGA-TS) (IGA score of 0 or 1 with a ≥ 2 -grade improvement from Baseline) at Week 16
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End point description:

The IGA for chronic prurigo considers the number of pruriginous lesions, which includes papules, nodules, plaques, umbilicated ulcers, and ulcers, and uses them as an overall severity rating on a scale of 0 to 4. 0: clear; no pruriginous lesions (0 lesions). 1: almost clear; rare palpable pruriginous lesions (approximately 1-5 lesions). 2: mild; few palpable pruriginous lesions (approximately 6-19 lesions). 3: moderate; many palpable pruriginous lesions (approximately 20-100 lesions). 4: severe; abundant palpable pruriginous lesions (over 100 lesions). The IGA-TS is defined as an IGA score of 0 or 1 with a ≥ 2 -grade improvement from Baseline. Missing post-Baseline values were imputed as non-responders. The 95% confidence interval was based on the Clopper-Pearson exact method.

End point type	Secondary
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End point timeframe:

Baseline; Week 16

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[8]	36 ^[9]	36 ^[10]	37 ^[11]
Units: percentage of participants				
number (confidence interval 95%)	5.4 (0.7 to 18.2)	13.9 (4.7 to 29.5)	30.6 (16.3 to 48.1)	48.6 (31.9 to 65.6)

Notes:

[8] - ITT Population

[9] - ITT Population

[10] - ITT Population

[11] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Time to ≥ 4 -point improvement from Baseline in Itch NRS score

End point title	Time to ≥ 4 -point improvement from Baseline in Itch NRS score
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End point description:

Each evening, the participants assessed their worst level of itch during the past 24 hours on a scale of 0 (no itch) to 10 (worst itch imaginable). The Baseline Itch NRS score was determined by averaging the 7 daily Itch NRS scores before Day 1. If ≥ 4 of the 7 days of the daily Itch NRS scores were missing prior to Day 1, then the Baseline Itch NRS score was set to "missing." The by-visit Itch NRS score for postbaseline visits was determined by averaging the 7 daily Itch NRS scores before the visit day. If 4 or more daily Itch NRS scores out of the 7 days before the visit day were missing, the Itch NRS score at the visit was set to missing. The time to a ≥ 4 -point improvement from Baseline in itch NRS score was estimated using the Kaplan-Meier method. -9999, 9999=value was not estimable because too few participants achieved a ≥ 4 -point improvement from Baseline in itch NRS score.

End point type	Secondary
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End point timeframe:

up to 122 days

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36 ^[12]	35 ^[13]	34 ^[14]	36 ^[15]
Units: days				
median (confidence interval 95%)	9999 (-9999 to 9999)	58.0 (16.0 to 9999)	35.0 (21.0 to 9999)	19.0 (13.0 to 47.0)

Notes:

[12] - ITT Population. Only participants with available data were analyzed.

[13] - ITT Population. Only participants with available data were analyzed.

[14] - ITT Population. Only participants with available data were analyzed.

[15] - ITT Population. Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: PC Period: Number of participants with any treatment-emergent adverse event (TEAE)

End point title	PC Period: Number of participants with any treatment-emergent adverse event (TEAE)
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End point description:

An adverse event (AE) is any untoward medical occurrence associated with the use of a drug in humans, whether or not it is considered drug related. An AE can therefore be any unfavorable or unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study drug. A TEAE is any AE either reported for the first time or the worsening of a pre-existing event after the first dose of study drug up to 30 days after the last dose of study drug. Analysis was conducted in members of the Safety Population, comprised of all participants who received at least 1 dose of study drug. Treatment groups for this population were determined according to the actual treatment the participant received on Day 1.

End point type	Secondary
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End point timeframe:

up to 152 days

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[16]	36 ^[17]	35 ^[18]	37 ^[19]
Units: participants	20	20	25	28

Notes:

[16] - Safety Population

[17] - Safety Population

[18] - Safety Population

[19] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: PC Period: Number of participants with any ≥Grade 3 TEAE

End point title	PC Period: Number of participants with any ≥Grade 3 TEAE
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End point description:

A TEAE is any AE either reported for the first time or the worsening of a pre-existing event after the first

dose of study drug up to 30 days after the last dose of study drug. The severity of AEs was assessed using Common Terminology Criteria for Adverse Events version 5.0 Grades 1 through 5. The investigator made an assessment of intensity for each AE and serious adverse event (SAE) reported during the study and assigned it to 1 of the following categories. Grade 1: mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; treatment not indicated. Grade 2: moderate; minimal, local, or noninvasive treatment indicated; limiting age-appropriate activities of daily living. Grade 3: severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living. Grade 4: life-threatening consequences; urgent treatment indicated. Grade 5: fatal.

End point type	Secondary
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End point timeframe:

up to 152 days

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37 ^[20]	36 ^[21]	35 ^[22]	37 ^[23]
Units: participants	0	1	1	2

Notes:

[20] - Safety Population

[21] - Safety Population

[22] - Safety Population

[23] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Extension Period: Number of participants with any TEAE

End point title	Extension Period: Number of participants with any TEAE
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End point description:

An AE is any untoward medical occurrence associated with the use of a drug in humans, whether or not it is considered drug related. An AE can therefore be any unfavorable or unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study drug. A TEAE is any AE either reported for the first time or the worsening of a pre-existing event after the first dose of study drug up to 30 days after the last dose of study drug. Analysis was conducted in members of the Extension Evaluable Population, comprised of all participants who received at least 1 dose of povorcitinib during the Extension Period.

End point type	Secondary
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End point timeframe:

up to 215 days

End point values	Placebo to povorcitinib 45 mg	Povorcitinib 15 mg to 45 mg	Povorcitinib 45 mg	Povorcitinib 75 mg to 45 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[24]	4 ^[25]	8 ^[26]	15 ^[27]
Units: participants	0	3	5	7

Notes:

[24] - Extension Evaluable Population

[25] - Extension Evaluable Population

[26] - Extension Evaluable Population

[27] - Extension Evaluable Population

End point values	Placebo to povorcitinib 75 mg	Povorcitinib 15 mg to 75 mg	Povorcitinib 45 mg to 75 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30 ^[28]	25 ^[29]	23 ^[30]	18 ^[31]
Units: participants	20	19	16	13

Notes:

[28] - Extension Evaluable Population

[29] - Extension Evaluable Population

[30] - Extension Evaluable Population

[31] - Extension Evaluable Population

Statistical analyses

No statistical analyses for this end point

Secondary: Extension Period: Number of participants with any ≥Grade 3 TEAE

End point title	Extension Period: Number of participants with any ≥Grade 3 TEAE
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End point description:

A TEAE is any AE either reported for the first time or the worsening of a pre-existing event after the first dose of study drug up to 30 days after the last dose of study drug. The severity of AEs was assessed using Common Terminology Criteria for Adverse Events version 5.0 Grades 1 through 5. The investigator made an assessment of intensity for each AE and serious adverse event (SAE) reported during the study and assigned it to 1 of the following categories. Grade 1: mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; treatment not indicated. Grade 2: moderate; minimal, local, or noninvasive treatment indicated; limiting age-appropriate activities of daily living. Grade 3: severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living. Grade 4: life-threatening consequences; urgent treatment indicated. Grade 5: fatal.

End point type	Secondary
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End point timeframe:

up to 215 days

End point values	Placebo to povorcitinib 45 mg	Povorcitinib 15 mg to 45 mg	Povorcitinib 45 mg	Povorcitinib 75 mg to 45 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[32]	4 ^[33]	8 ^[34]	15 ^[35]
Units: participants	0	0	0	1

Notes:

[32] - Extension Evaluable Population

[33] - Extension Evaluable Population

[34] - Extension Evaluable Population

[35] - Extension Evaluable Population

End point values	Placebo to povorcitinib 75 mg	Povorcitinib 15 mg to 75 mg	Povorcitinib 45 mg to 75 mg	Povorcitinib 75 mg
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	mg			
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30 ^[36]	25 ^[37]	23 ^[38]	18 ^[39]
Units: participants	0	1	3	3

Notes:

[36] - Extension Evaluable Population

[37] - Extension Evaluable Population

[38] - Extension Evaluable Population

[39] - Extension Evaluable Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

from the time of Informed Consent Form signing until at least 30 days after the last dose of study drug (up to approximately 44 weeks)

Adverse event reporting additional description:

Adverse events were collected in members of the Safety Population, comprised of all participants who received at least 1 dose of study drug, and the Extension Evaluable Population, comprised of all participants who received at least 1 dose of povorcitinib during the Extension Period.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

On Day 1, participants were randomized to receive matching placebo once daily (QD) and stratified by Investigator's Global Assessment (IGA) score (3 versus 4). Participants received blinded placebo through Week 16.

Reporting group title	Placebo to povorcitinib 75 mg
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Reporting group description:

On Day 1, participants were randomized to receive placebo QD and stratified by IGA score (3 versus 4). Participants received blinded placebo through Week 16. Based on a lack of efficacy response at Week 16 (not meeting the definition of a responder), these participants received povorcitinib 75 mg QD for an additional 24 weeks in the extension period.

Reporting group title	Povorcitinib 15 mg
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Reporting group description:

On Day 1, participants were randomized to receive povorcitinib 15 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16.

Reporting group title	Placebo to povorcitinib 45 mg
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Reporting group description:

On Day 1, participants were randomized to receive placebo QD and stratified by IGA score (3 versus 4). Participants received blinded placebo through Week 16. Based on their efficacy response at Week 16 (≥ 4 -point decrease in Itch Numerical Rating Scale [NRS] score and IGA-Treatment Success and no administration of rescue therapy during the placebo-controlled period), these participants received povorcitinib 45 milligrams (mg) QD for an additional 24 weeks in the extension period.

Reporting group title	Povorcitinib 15 mg to 45 mg
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Reporting group description:

On Day 1, participants were randomized to receive povorcitinib 15 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16. Based on their efficacy response at Week 16 (≥ 4 -point decrease in Itch NRS score and IGA-Treatment Success and no administration of rescue therapy during the placebo-controlled period), these participants received povorcitinib 45 mg QD for an additional 24 weeks in the extension period.

Reporting group title	Povorcitinib 45 mg to 75 mg
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Reporting group description:

On Day 1, participants were randomized to receive povorcitinib 45 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16. Based on a lack of efficacy response at Week 16 (not meeting the definition of a responder), these participants received povorcitinib 75 mg QD for an additional 24 weeks in the extension period.

Reporting group title	Povorcitinib 15 mg to 75 mg
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Reporting group description:

On Day 1, participants were randomized to receive povorcitinib 15 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16. Based on a lack of efficacy response at Week 16 (not meeting the definition of a responder), these participants received povorcitinib 75 mg QD for an additional 24 weeks in the extension period.

Reporting group title	Povorcitinib 45 mg
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Reporting group description:

Participants received povorcitinib 45 mg in both the placebo-controlled period and the treatment extension period. On Day 1, participants were randomized to receive povorcitinib 45 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16. Based on their efficacy response at Week 16 (≥ 4 -point decrease in Itch NRS score and IGA-TS and no administration of rescue therapy during the placebo-controlled period), these participants received povorcitinib 45 mg QD for an additional 24 weeks in the extension period.

Reporting group title	Povorcitinib 75 mg to 45 mg
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Reporting group description:

On Day 1, participants were randomized to receive povorcitinib 75 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16. Based on their efficacy response at Week 16 (≥ 4 -point decrease in Itch NRS score and IGA-Treatment Success and no administration of rescue therapy during the placebo-controlled period), these participants received povorcitinib 45 mg QD for an additional 24 weeks in the extension period.

Reporting group title	Povorcitinib 75 mg
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Reporting group description:

Participants received povorcitinib 75 mg in both the placebo-controlled period and the treatment extension period. On Day 1, participants were randomized to receive povorcitinib 75 mg QD and stratified by IGA score (3 versus 4). Participants received blinded study drug through Week 16. Based on a lack of efficacy response at Week 16 (not meeting the definition of a responder), these participants received povorcitinib 75 mg QD for an additional 24 weeks in the extension period.

Serious adverse events	Placebo	Placebo to povorcitinib 75 mg	Povorcitinib 15 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	1 / 30 (3.33%)	2 / 7 (28.57%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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
Colitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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
Respiratory, thoracic and mediastinal disorders			
Nasal septum deviation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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
Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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
Neurodermatitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 30 (3.33%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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
Myopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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
Erysipelas			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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
Mastitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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
Tooth infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (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	Placebo to povorcitinib 45 mg	Povorcitinib 15 mg to 45 mg	Povorcitinib 45 mg to 75 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	5 / 23 (21.74%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (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

General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Respiratory, thoracic and mediastinal disorders			
Nasal septum deviation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Neurodermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Musculoskeletal and connective tissue disorders			

Intervertebral disc protrusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Mastitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Tooth infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (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	Povorcitinib 15 mg to 75 mg	Povorcitinib 45 mg	Povorcitinib 75 mg to 45 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 25 (4.00%)	1 / 12 (8.33%)	2 / 15 (13.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (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
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (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
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (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
Respiratory, thoracic and mediastinal disorders			
Nasal septum deviation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (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
Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (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
Neurodermatitis			

subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (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
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (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
Myopathy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (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
COVID-19			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (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
Erysipelas			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (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
Mastitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (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

Pneumonia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Povorcitinib 75 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 22 (18.18%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Nasal septum deviation			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neurodermatitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myopathy			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mastitis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tooth infection			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Placebo	Placebo to povorcitinib 75 mg	Povorcitinib 15 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 6 (33.33%)	19 / 30 (63.33%)	4 / 7 (57.14%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 30 (3.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	3 / 30 (10.00%) 3	1 / 7 (14.29%) 1
Mucosal dryness subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Reproductive system and breast disorders Ejaculation failure subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Uterine polyp subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 30 (6.67%) 2	0 / 7 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Investigations Aspergillus test positive subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0

Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 30 (6.67%) 2	0 / 7 (0.00%) 0
Haemoglobin decreased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	3 / 30 (10.00%) 3	0 / 7 (0.00%) 0
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Joint capsule rupture subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Muscle strain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Ligament sprain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 30 (3.33%) 1	1 / 7 (14.29%) 1
Cardiac disorders Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 30 (3.33%) 1	0 / 7 (0.00%) 0

Intercostal neuralgia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Migraine subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 30 (3.33%) 1	1 / 7 (14.29%) 1
Polyneuropathy subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Presyncope subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Blood and lymphatic system disorders Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 30 (6.67%) 2	0 / 7 (0.00%) 0
Ear and labyrinth disorders Ear discomfort subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Eye disorders Blepharospasm subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Blepharitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Eye pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	2 / 30 (6.67%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 30 (3.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Loose tooth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Trichoglossia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 30 (3.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dermatitis contact			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diffuse alopecia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lichen myxoedematosus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 6 (0.00%)	4 / 30 (13.33%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
Perioral dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rosacea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Trichorrhexis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Urinary incontinence subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Back pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Pain in jaw subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Spinal pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Infections and infestations			
Asymptomatic bacteriuria subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Cellulitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 30 (3.33%) 1	0 / 7 (0.00%) 0
COVID-19 subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	3 / 30 (10.00%) 3	1 / 7 (14.29%) 1
Bronchitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 30 (6.67%) 3	0 / 7 (0.00%) 0
Cystitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 30 (0.00%) 0	0 / 7 (0.00%) 0
Eyelid folliculitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	3 / 30 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Gastrointestinal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 6 (16.67%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	5 / 30 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	7	0
Otitis externa			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	1 / 30 (3.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 30 (3.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			

subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Skin candida			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 6 (0.00%)	2 / 30 (6.67%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Tonsillitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 30 (3.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	2 / 30 (6.67%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 6 (0.00%)	0 / 30 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Non-serious adverse events	Placebo to povorcitinib 45 mg	Povorcitinib 15 mg to 45 mg	Povorcitinib 45 mg to 75 mg
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 1 (0.00%)	3 / 4 (75.00%)	20 / 23 (86.96%)
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1	2 / 23 (8.70%) 2
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all) Chest pain subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Mucosal dryness subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 2 / 4 (50.00%) 2 0 / 4 (0.00%) 0	0 / 23 (0.00%) 0 1 / 23 (4.35%) 1 3 / 23 (13.04%) 3 0 / 23 (0.00%) 0
Reproductive system and breast disorders Ejaculation failure subjects affected / exposed occurrences (all) Uterine polyp subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	0 / 4 (0.00%) 0 1 / 4 (25.00%) 1	0 / 23 (0.00%) 0 0 / 23 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Epistaxis	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0	1 / 23 (4.35%) 1 2 / 23 (8.70%) 2

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1	0 / 23 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	1 / 23 (4.35%) 1
Investigations Aspergillus test positive subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	4 / 23 (17.39%) 4
Haemoglobin decreased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	3 / 23 (13.04%) 3
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1	2 / 23 (8.70%) 2
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1	2 / 23 (8.70%) 2
Joint capsule rupture subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Muscle strain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Ligament sprain			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Cardiac disorders Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	1 / 23 (4.35%) 1
Headache subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 4 (25.00%) 2	4 / 23 (17.39%) 7
Intercostal neuralgia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Migraine subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Polyneuropathy subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Presyncope subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1	0 / 23 (0.00%) 0
Blood and lymphatic system disorders Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Ear and labyrinth disorders Ear discomfort subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1	0 / 23 (0.00%) 0
Vertigo			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Loose tooth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Trichoglossia			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Dermatitis contact			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Diffuse alopecia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Lichen myxoedematosus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Perioral dermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rosacea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1

Skin mass subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1	0 / 23 (0.00%) 0
Trichorrhexis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	1 / 23 (4.35%) 1
Pollakiuria subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	4 / 23 (17.39%) 4
Myalgia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1	0 / 23 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1	1 / 23 (4.35%) 1
Pain in jaw subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Spinal pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Infections and infestations Asymptomatic bacteriuria subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1	0 / 23 (0.00%) 0

Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Eyelid folliculitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	3 / 23 (13.04%)
occurrences (all)	0	0	3
Gastroenteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Gastrointestinal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Herpes zoster			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	2 / 23 (8.70%)
occurrences (all)	0	1	4

Otitis externa			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 23 (4.35%)
occurrences (all)	0	2	1
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Metabolism and nutrition disorders			
Hypercholesterolaemia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Increased appetite subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0

Non-serious adverse events	Povorcitinib 15 mg to 75 mg	Povorcitinib 45 mg	Povorcitinib 75 mg to 45 mg
Total subjects affected by non-serious adverse events subjects affected / exposed	19 / 25 (76.00%)	7 / 12 (58.33%)	12 / 15 (80.00%)
Vascular disorders			
Hypertension subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 12 (0.00%) 0	0 / 15 (0.00%) 0
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	1 / 15 (6.67%) 1
Chest pain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 12 (8.33%) 1	0 / 15 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	4 / 25 (16.00%) 6	0 / 12 (0.00%) 0	2 / 15 (13.33%) 2
Mucosal dryness subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	1 / 15 (6.67%) 1
Reproductive system and breast disorders			

Ejaculation failure subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	1 / 15 (6.67%) 1
Uterine polyp subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	0 / 15 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Asthma subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	0 / 15 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	0 / 12 (0.00%) 0	1 / 15 (6.67%) 1
Epistaxis subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 12 (8.33%) 1	0 / 15 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	1 / 12 (8.33%) 1	0 / 15 (0.00%) 0
Psychiatric disorders			
Depression subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	0 / 15 (0.00%) 0
Investigations			
Aspergillus test positive subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	1 / 15 (6.67%) 1
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	1 / 12 (8.33%) 2	1 / 15 (6.67%) 1
Haemoglobin decreased subjects affected / exposed occurrences (all)	5 / 25 (20.00%) 6	0 / 12 (0.00%) 0	3 / 15 (20.00%) 3
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	1 / 15 (6.67%) 2

Weight increased subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 12 (8.33%) 1	0 / 15 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	0 / 15 (0.00%) 0
Joint capsule rupture subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	1 / 15 (6.67%) 1
Muscle strain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	1 / 15 (6.67%) 1
Ligament sprain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	0 / 15 (0.00%) 0
Cardiac disorders			
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	1 / 15 (6.67%) 1
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 12 (8.33%) 1	1 / 15 (6.67%) 1
Headache subjects affected / exposed occurrences (all)	6 / 25 (24.00%) 6	2 / 12 (16.67%) 2	0 / 15 (0.00%) 0
Intercostal neuralgia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	1 / 15 (6.67%) 1
Migraine subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 12 (8.33%) 2	0 / 15 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	0 / 15 (0.00%) 0

Polyneuropathy subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 12 (8.33%) 1	0 / 15 (0.00%) 0
Presyncope subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	0 / 15 (0.00%) 0
Blood and lymphatic system disorders Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	1 / 15 (6.67%) 1
Ear and labyrinth disorders Ear discomfort subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	0 / 15 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	1 / 15 (6.67%) 1
Eye disorders Blepharospasm subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 12 (8.33%) 1	0 / 15 (0.00%) 0
Blepharitis subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 12 (8.33%) 1	0 / 15 (0.00%) 0
Eye pain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 12 (8.33%) 1	0 / 15 (0.00%) 0
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	2 / 15 (13.33%) 2
Constipation subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 12 (0.00%) 0	0 / 15 (0.00%) 0
Dry mouth subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 2	1 / 12 (8.33%) 1	0 / 15 (0.00%) 0

Dyspepsia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Loose tooth			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	3 / 25 (12.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	4	1	0
Trichoglossia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Diffuse alopecia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Lichen myxoedematosus			

subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Neurodermatitis			
subjects affected / exposed	3 / 25 (12.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	3	1	1
Perioral dermatitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
Rosacea			
subjects affected / exposed	2 / 25 (8.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	2	1	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Skin mass			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Trichorrhexis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Urinary incontinence			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	4 / 25 (16.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	4	1	0
Myalgia			

subjects affected / exposed	1 / 25 (4.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	1 / 25 (4.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Spinal pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 25 (4.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	2	1	0
COVID-19			
subjects affected / exposed	3 / 25 (12.00%)	2 / 12 (16.67%)	1 / 15 (6.67%)
occurrences (all)	3	2	1
Bronchitis			
subjects affected / exposed	0 / 25 (0.00%)	2 / 12 (16.67%)	2 / 15 (13.33%)
occurrences (all)	0	2	2
Cystitis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Eyelid folliculitis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1

Gastrointestinal infection			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Herpes zoster			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 25 (0.00%)	1 / 12 (8.33%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Nasopharyngitis			
subjects affected / exposed	3 / 25 (12.00%)	2 / 12 (16.67%)	4 / 15 (26.67%)
occurrences (all)	5	2	4
Otitis externa			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	1 / 25 (4.00%)	1 / 12 (8.33%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Pneumonia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Pulpitis dental			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Skin infection			
subjects affected / exposed	1 / 25 (4.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Tooth infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 25 (4.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	1 / 25 (4.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	4
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	2 / 25 (8.00%)	0 / 12 (0.00%)	2 / 15 (13.33%)
occurrences (all)	2	0	2
Hyperkalaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Increased appetite			
subjects affected / exposed	0 / 25 (0.00%)	0 / 12 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Povorcitinib 75 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 22 (63.64%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
General disorders and administration site conditions			

<p>Asthenia</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Chest pain</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Fatigue</p> <p>subjects affected / exposed</p> <p>1 / 22 (4.55%)</p> <p>occurrences (all)</p> <p>1</p>			
<p>Mucosal dryness</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Reproductive system and breast disorders</p> <p>Ejaculation failure</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Uterine polyp</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Respiratory, thoracic and mediastinal disorders</p> <p>Asthma</p> <p>subjects affected / exposed</p> <p>2 / 22 (9.09%)</p> <p>occurrences (all)</p> <p>2</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>1 / 22 (4.55%)</p> <p>occurrences (all)</p> <p>1</p> <p>Epistaxis</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Oropharyngeal pain</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Psychiatric disorders</p> <p>Depression</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			

Investigations			
Aspergillus test positive			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Haemoglobin decreased			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	5		
Platelet count decreased			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Weight increased			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	2		
Joint capsule rupture			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Muscle strain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			

subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Headache			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Intercostal neuralgia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Polyneuropathy			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Blepharitis			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Eye pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dry mouth			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dysphagia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Loose tooth			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	3		
Trichoglossia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dermatitis contact			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Diffuse alopecia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Lichen myxoedematosus			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Neurodermatitis			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Perioral dermatitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Rosacea			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Skin mass			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Trichorrhexis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			

Dysuria			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Urinary incontinence			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Myalgia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pain in jaw			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Spinal pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	2		
COVID-19			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Bronchitis			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Eyelid folliculitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Folliculitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Gastrointestinal infection			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Herpes zoster			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Herpes simplex			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Influenza			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Otitis externa			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Oral herpes			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Oral candidiasis			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Pulpitis dental			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Skin candida			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Skin infection			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Tooth infection			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Tonsillitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		

Hyperkalaemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Increased appetite			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 July 2021	The primary purpose of the amendment was to change the inclusion criteria associated with the minimum number of nodules, to include a sub-study for itch and sleep monitoring assessment, and to revise the interim analysis.
06 May 2022	The primary purpose of the amendment was to remove the interim analysis, modify the exclusion criteria associated with estimated glomerular filtration rate; to add clarification on the types of prurigo nodularis lesions being assessed; and to add clarification on the management of creatine kinase elevations.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported