Clinical trial results:
A Phase 3, Double-Blind, Randomized, 8-Week, Vehicle-Controlled Efficacy and Safety Study of Ruxolitinib Cream Followed by a Long-Term Safety Extension Period in Adolescents and Adults With Atopic Dermatitis

Summary

EudraCT number	2018-003713-18
Trial protocol	CZ DE BG PL ES
Global end of trial date	09 November 2020

Results information

Result version number	v1 (current)
This version publication date	04 December 2021
First version publication date	04 December 2021

Trial information

Trial identification

Sponsor protocol code	INCB 18424-304

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	09 November 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 November 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to assess the efficacy of ruxolitinib cream in adolescents and adults with atopic dermatitis (AD).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 December 2018
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	11 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Bulgaria: 35
Country: Number of subjects enrolled	Canada: 6
Country: Number of subjects enrolled	Czechia: 88
Country: Number of subjects enrolled	Germany: 9
Country: Number of subjects enrolled	Poland: 63
Country: Number of subjects enrolled	Spain: 8
Country: Number of subjects enrolled	United States: 409
Worldwide total number of subjects	618
EEA total number of subjects	203

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)	122
Adults (18-64 years)	439
From 65 to 84 years	56
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

A total of 618 participants were enrolled at 65 investigative sites in North America and Europe from December 20, 2018 to November 09, 2020.

Pre-assignment

Screening details:

Participants in Vehicle Control (VC) Period with no safety concerns at week 8 continued in the 44-week Long Term Safety (LTS) Period and equally randomized into 1 of the 2 active treatment groups. Participants who were on active treatment during the VC Period continued with the same treatment regimen in the LTS Period

Period 1

Period 1 title	Vehicle Control Period (Day 1 to Week 8)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Carer, Subject, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	VC Period: Vehicle Cream BID

Arm description:

Ruxolitinib matching vehicle cream applied topically to the affected areas as a thin film twice daily (BID) 8 hours apart from Day 1 up to Week 8.

Arm type	Placebo
Investigational medicinal product name	Vehicle Cream
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Twice Daily

Arm title	VC Period: Ruxolitinib 0.75% Cream BID

Arm description:

Ruxolitinib 0.75% cream, applied topically to the affected areas as a thin film BID 8 hours apart from Day 1 up to Week 8.

Arm type	Experimental
Investigational medicinal product name	ruxolitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

0.75% cream Twice Daily

Arm title	VC Period: Ruxolitinib 1.5% Cream BID

Arm description:

Ruxolitinib 1.5% cream, applied topically to the affected areas as a thin film BID 8 hours apart from Day 1 up to Week 8.

Arm type	Experimental

Investigational medicinal product name	ruxolitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

1.5% cream Twice Daily

Number of subjects in period 1	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID
Started	124	248	246
Completed	105	209	224
Not completed	19	39	22
Physician decision	3	-	1
Consent withdrawn by subject	11	21	15
Adverse event, non-fatal	1	1	-
Lost to follow-up	3	13	4
Reason not Specified	1	2	2
Protocol deviation	-	2	-

Period 2

Period 2 title	Long-Term Safety Period (Weeks 8 to 52)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID

Arm description:

Participants who applied vehicle cream during the VC Period were randomized at Week 8 to apply ruxolitinib 0.75% cream, topically to the affected areas as a thin film BID as needed from Week 9 up to Week 52.

Arm type	Experimental
Investigational medicinal product name	ruxolitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

0.75% cream twice daily

Arm title	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID

Arm description:	
Participants who applied vehicle cream during the VC Period were randomized at Week 8 to apply ruxolitinib 1.5% cream, topically to the affected areas as a thin film BID as needed from Week 9 up to Week 52.	
Arm type	Experimental
Investigational medicinal product name	ruxolitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use
Dosage and administration details:	
1.5% cream twice daily	
Arm title	LTS Period: Ruxolitinib 0.75% Cream BID
Arm description:	
Participants who applied ruxolitinib 0.75% cream during the VC Period, continued applying ruxolitinib 0.75% cream, topically to the affected areas as a thin film BID as needed from Week 9 up to Week 52.	
Arm type	Experimental
Investigational medicinal product name	ruxolitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use
Dosage and administration details:	
0.75% cream twice daily	
Arm title	LTS Period: Ruxolitinib 1.5% Cream BID
Arm description:	
Participants who applied ruxolitinib 1.5% cream during the VC Period, continued applying ruxolitinib 1.5% cream, topically to the affected areas as a thin film BID as needed from Week 9 up to Week 52.	
Arm type	Experimental
Investigational medicinal product name	ruxolitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use
Dosage and administration details:	
1.5% cream twice daily	

Number of subjects in period 2[1]	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID	LTS Period: Ruxolitinib 0.75% Cream BID
Started	53	52	204
Completed	33	41	151
Not completed	20	11	53
Physician decision	1	-	4
Consent withdrawn by subject	12	8	26
Adverse event, non-fatal	-	-	4
Pregnancy	1	-	-
Lost to follow-up	4	2	13

Reason not Specified	1	1	1
Lack of efficacy	1	-	4
Protocol deviation	-	-	1

Number of subjects in period 2[1]	LTS Period: Ruxolitinib 1.5% Cream BID
Started	221
Completed	170
Not completed	51
Physician decision	2
Consent withdrawn by subject	34
Adverse event, non-fatal	-
Pregnancy	1
Lost to follow-up	10
Reason not Specified	-
Lack of efficacy	4
Protocol deviation	-

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: As per disposition table some subjects discontinued the study after vehicle period, and the participants from vehicle period are randomly assigned to one of the treatment groups in LTS period.

Baseline characteristics

Reporting groups	
Reporting group title	VC Period: Vehicle Cream BID
Reporting group description:	
Ruxolitinib matching vehicle cream applied topically to the affected areas as a thin film twice daily (BID) 8 hours apart from Day 1 up to Week 8.	
Reporting group title	VC Period: Ruxolitinib 0.75% Cream BID
Reporting group description:	
Ruxolitinib 0.75% cream, applied topically to the affected areas as a thin film BID 8 hours apart from Day 1 up to Week 8.	
Reporting group title	VC Period: Ruxolitinib 1.5% Cream BID
Reporting group description:	
Ruxolitinib 1.5% cream, applied topically to the affected areas as a thin film BID 8 hours apart from Day 1 up to Week 8.	

Reporting group values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects	124	248	246
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)	22	55	45
Adults (18-64 years)	87	171	181
From 65-84 years	15	22	19
85 years and over	0	0	1
Age Continuous Units: years			
arithmetic mean	38.9	35.8	35.9
standard deviation	± 18.90	± 18.45	± 18.01
Sex: Female, Male Units: participants			
Female	80	150	150
Male	44	98	96
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	17	31	30
Not Hispanic or Latino	107	217	216
Race/Ethnicity, Customized Units: Subjects			
White/Caucasian	85	174	178
Black/African-American	32	63	57
Asian	2	6	6
American-Indian/Alaska Native	0	0	1

Native Hawaiian/Pacific Islander	2	0	0
Other	3	5	4

Body Mass Index Units: Kilograms per square metre (kg/m^2)			
arithmetic mean	27.75	27.60	28.01
standard deviation	± 6.737	± 7.091	± 7.495

Reporting group values	Total		
Number of subjects	618		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	122		
Adults (18-64 years)	439		
From 65-84 years	56		
85 years and over	1		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: participants			
Female	380		
Male	238		
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	78		
Not Hispanic or Latino	540		
Race/Ethnicity, Customized Units: Subjects			
White/Caucasian	437		
Black/African-American	152		
Asian	14		
American-Indian/Alaska Native	1		
Native Hawaiian/Pacific Islander	2		
Other	12		
Body Mass Index Units: Kilograms per square metre (kg/m^2)			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

Reporting group title	VC Period: Vehicle Cream BID
Reporting group description:	
Ruxolitinib matching vehicle cream applied topically to the affected areas as a thin film twice daily (BID) 8 hours apart from Day 1 up to Week 8.	
Reporting group title	VC Period: Ruxolitinib 0.75% Cream BID
Reporting group description:	
Ruxolitinib 0.75% cream, applied topically to the affected areas as a thin film BID 8 hours apart from Day 1 up to Week 8.	
Reporting group title	VC Period: Ruxolitinib 1.5% Cream BID
Reporting group description:	
Ruxolitinib 1.5% cream, applied topically to the affected areas as a thin film BID 8 hours apart from Day 1 up to Week 8.	
Reporting group title	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID
Reporting group description:	
Participants who applied vehicle cream during the VC Period were randomized at Week 8 to apply ruxolitinib 0.75% cream, topically to the affected areas as a thin film BID as needed from Week 9 up to Week 52.	
Reporting group title	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID
Reporting group description:	
Participants who applied vehicle cream during the VC Period were randomized at Week 8 to apply ruxolitinib 1.5% cream, topically to the affected areas as a thin film BID as needed from Week 9 up to Week 52.	
Reporting group title	LTS Period: Ruxolitinib 0.75% Cream BID
Reporting group description:	
Participants who applied ruxolitinib 0.75% cream during the VC Period, continued applying ruxolitinib 0.75% cream, topically to the affected areas as a thin film BID as needed from Week 9 up to Week 52.	
Reporting group title	LTS Period: Ruxolitinib 1.5% Cream BID
Reporting group description:	
Participants who applied ruxolitinib 1.5% cream during the VC Period, continued applying ruxolitinib 1.5% cream, topically to the affected areas as a thin film BID as needed from Week 9 up to Week 52.	

Primary: Percentage of Participants Who Achieved Investigator's Global Assessment – Treatment Success (IGA-TS) at Week 8

End point title	Percentage of Participants Who Achieved Investigator's Global Assessment – Treatment Success (IGA-TS) at Week 8
End point description:	
The IGA is an overall eczema severity rating on a 5-point scale ranging from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, induration/papulation, and oozing/crusting. The IGA-TS is defined as an IGA score of 0 (clear skin) or 1 (almost clear skin) with ≥ 2 grade improvement from Baseline.	
End point type	Primary
End point timeframe:	
Baseline to Week 8	

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: percentage of participants				
number (confidence interval 95%)	7.6 (3.5 to 14.0)	39.0 (32.6 to 45.6)	51.3 (44.6 to 58.0)	

Statistical analyses

Statistical analysis title	Exact Logistic regression
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [1]
Method	Conditional Exact Test
Parameter estimate	Odds ratio (OR)
Point estimate	8.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.125
upper limit	21.202

Notes:

[1] - The unadjusted p-values between each treatment group and vehicle were calculated based on Conditional Exact test.

Statistical analysis title	Exact Logistic regression
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [2]
Method	Conditional Exact Test
Parameter estimate	Odds ratio (OR)
Point estimate	15.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.354
upper limit	38.061

Notes:

[2] - The unadjusted p-values between each treatment group and vehicle were calculated based on Conditional Exact test.

Secondary: Proportion of Participants Who Achieved Eczema Area and Severity Index 75 (EASI75) at Week 8

End point title	Proportion of Participants Who Achieved Eczema Area and Severity Index 75 (EASI75) at Week 8

End point description:

EASI scoring system examines 4 areas of the body (head/neck, trunk, upper limbs, and lower limbs) and weights them for participants of at least 8 years of age. Each of the 4 body regions is assessed separately for erythema (E), induration/papulation/edema (I), excoriations (Ex), and lichenification (l) each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe). Half scores are allowed between severities 1, 2 and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 and the severity strata are as follows: 0 = clear; 0.1 to 1.0 = almost clear; 1.1 to 7.0 = mild; 7.1 to 21.0 = moderate; 21.1 to 50.0 = severe; 50.1 to 72.0 = very severe. An EASI75 responder was defined as a participant achieving 75% or greater improvement from Baseline in EASI score.

End point type	Secondary

End point timeframe:

Baseline to Week 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: percentage of participants				
number (confidence interval 95%)	14.4 (8.6 to 22.1)	51.5 (44.9 to 58.1)	61.8 (55.2 to 68.2)	

Statistical analyses

Statistical analysis title	Exact Logistic regression
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [3]
Method	Conditional Exact Test
Parameter estimate	Odds ratio (OR)
Point estimate	10.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.775
upper limit	20.732

Notes:

[3] - The unadjusted p-values between each treatment group and vehicle were calculated based on Conditional Exact test.

Statistical analysis title	Exact Logistic regression
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID

Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [4]
Method	Conditional Exact Test
Parameter estimate	Odds ratio (OR)
Point estimate	6.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.723
upper limit	13.184

Notes:

[4] - The unadjusted p-values between each treatment group and vehicle were calculated based on Conditional Exact test.

Secondary: Percentage of Participants With a ≥ 4-Point Improvement in Itch Numerical Rating Scale (NRS) Score From Baseline to Week 8

End point title	Percentage of Participants With a ≥ 4-Point Improvement in Itch Numerical Rating Scale (NRS) Score From Baseline to Week 8

End point description:

The Itch NRS is a daily participant-reported measure (24-hour recall), of the worst level of itch using a diary. Participants are asked to rate the itching severity because of their AD by selecting a number from 0 (no itch) to 10 (worst imaginable itch) that best describes their worst level of itching in the past 24 hours.

End point type	Secondary

End point timeframe:

Baseline to Week 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	80	157	146	
Units: percentage of participants				
number (not applicable)	16.3	42.7	50.7	

Statistical analyses

Statistical analysis title	Exact Logistic regression
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID

Number of subjects included in analysis	226
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [5]
Method	Conditional Exact Test
Parameter estimate	Odds ratio (OR)
Point estimate	5.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.833
upper limit	12.657

Notes:

[5] - The unadjusted p-values between each treatment group and vehicle were calculated based on Conditional Exact test.

Statistical analysis title	Exact Logistic regression
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	237
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [6]
Method	Conditional Exact Test
Parameter estimate	Odds ratio (OR)
Point estimate	4.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.045
upper limit	9.036

Notes:

[6] - The unadjusted p-values between each treatment group and vehicle were calculated based on Conditional Exact test.

Secondary: Proportion of Participants With a Clinically Meaningful (≥ 6-Point) Improvement in the Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form – Sleep Disturbance (8b – 24-Hour Recall) Score at Week 8

End point title	Proportion of Participants With a Clinically Meaningful (≥ 6-Point) Improvement in the Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form – Sleep Disturbance (8b – 24-Hour Recall) Score at Week 8

End point description:

The PROMIS Short Form – Sleep Disturbance (8b) questionnaire assesses participant's self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep. This questionnaire is completed in the morning by the participant where each item asks the participant to rate the severity of the participant's sleep disturbance. It is a 5-point scale with a range in score from 8 to 40, with higher scores indicating greater severity of sleep disturbance.

End point type	Secondary

End point timeframe:

Baseline to Week 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	110	213	211	
Units: percentage of participants				
number (not applicable)	19.1	20.7	25.6	

Statistical analyses

Statistical analysis title	Exact Logistic regression
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	323
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8553 [7]
Method	Conditional Exact Test
Parameter estimate	Odds ratio (OR)
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.598
upper limit	2.094

Notes:

[7] - The unadjusted p-values between each treatment group and vehicle were calculated based on Conditional Exact test.

Statistical analysis title	Exact Logistic regression
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	321
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2359 [8]
Method	Conditional Exact Test
Parameter estimate	Odds ratio (OR)
Point estimate	1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.805
upper limit	2.741

Notes:

[8] - The unadjusted p-values between each treatment group and vehicle were calculated based on Conditional Exact test.

Secondary: Percentage of Participants With a Clinically Meaningful (≥ 6-Point) Improvement in the PROMIS Short Form – Sleep-Related Impairment (8a – 24-Hour Recall) Score at Week 8

End point title	Percentage of Participants With a Clinically Meaningful (≥ 6-Point) Improvement in the PROMIS Short Form – Sleep-Related Impairment (8a – 24-Hour Recall) Score at Week 8

End point description:

The PROMIS Short Form – Sleep-Related Impairment (8a) questionnaire assesses participant's self-reported perceptions of alertness, sleepiness, and tiredness during usual waking hours and the perceived functional impairments during wakefulness associated with sleep problems or impaired alertness. The questionnaire is filled in the evening where each item asks the participant to rate the severity of the participant's sleep impairment. It has 8 simple questions with a 5-point scale with a range in score from 8 to 40, with higher scores indicating greater severity of sleep-related impairment.

End point type	Secondary

End point timeframe:

Baseline to Week 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	111	215	212	
Units: percentage of participants				
number (not applicable)	13.5	20.0	23.1	

Statistical analyses

Statistical analysis title	Exact Logistic regression
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	326
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1784 [9]
Method	Conditional Exact Test
Parameter estimate	Odds ratio (OR)
Point estimate	1.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.827
upper limit	3.342

Notes:

[9] - The unadjusted p-values between each treatment group and vehicle were calculated based on Conditional Exact test.

Statistical analysis title	Exact Logistic regression
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID

Number of subjects included in analysis	323
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0472 [10]
Method	Conditional Exact Test
Parameter estimate	Odds ratio (OR)
Point estimate	1.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.007
upper limit	4

Notes:

[10] - The unadjusted p-values between each treatment group and vehicle were calculated based on Conditional Exact test.

Secondary: Percentage of Participants With at Least One Treatment-Emergent Adverse Event (TEAE) and Treatment-Emergent Serious Adverse Event (SAE) During the VC Period

End point title	Percentage of Participants With at Least One Treatment-Emergent Adverse Event (TEAE) and Treatment-Emergent Serious Adverse Event (SAE) During the VC Period

End point description:

An AE is any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug-related. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study treatment. A SAE is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect or an important medical event may be considered serious when, based on appropriate medical judgment, the event may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. A TEAE or treatment emergent SAE is any AE or SAE either reported for first time or worsening of a pre-existing event after first dose of study drug.

End point type	Secondary

End point timeframe:

From date of first application up to Week 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	124	248	246	
Units: percentage of participants				
number (not applicable)				
TEAE	31.5	29.0	23.6	
Treatment Emergent SAE	0.0	1.2	0.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With at Least One TEAE and Treatment Emergent SAE During the LTS Period

End point title	Percentage of Participants With at Least One TEAE and Treatment Emergent SAE During the LTS Period

End point description:

An AE is any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug-related. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study treatment. A SAE is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect or an important medical event may be considered serious when, based on appropriate medical judgment, the event may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. A TEAE or treatment emergent SAE is any AE or SAE either reported for first time or worsening of a pre-existing event after first dose of study drug.

End point type	Secondary

End point timeframe:

Week 8 until last follow-up visit (up to 52 weeks)

End point values	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID	LTS Period: Ruxolitinib 0.75% Cream BID	LTS Period: Ruxolitinib 1.5% Cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	52	204	221
Units: percentage of participants				
number (not applicable)				
TEAE	58.5	65.4	66.2	54.3
Treatment Emergent SAE	3.8	0.0	2.5	1.4

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an IGA-TS at Weeks 2 and 4

End point title	Percentage of Participants Who Achieved an IGA-TS at Weeks 2 and 4

End point description:

The IGA is an overall eczema severity rating on a 5-point scale ranging from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, induration/papulation, and oozing/crusting. The IGA-TS is defined as an IGA score of 0 (clear skin) or 1 (almost clear skin) with ≥ 2 grade improvement from Baseline.

End point type	Secondary

End point timeframe:

Baseline to Weeks 2 and 4

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: percentage of participants				
number (not applicable)				
Week 2	4.2	17.3	25.0	
Week 4	5.9	35.5	43.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving an IGA of 0 or 1 During the VC Period

End point title	Percentage of Participants Achieving an IGA of 0 or 1 During the VC Period

End point description:

The IGA is an overall eczema severity rating on a 5-point scale ranging from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, induration/papulation, and oozing/crusting.

End point type	Secondary

End point timeframe:

Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: percentage of participants				
number (not applicable)				
Week 2	9.3	24.2	34.6	
Week 4	16.9	45.9	52.6	
Week 8	16.1	51.1	62.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving an IGA of 0 or 1 During the LTS Period

End point title	Percentage of Participants Achieving an IGA of 0 or 1 During the LTS Period

End point description:

The IGA is an overall eczema severity rating on a 5-point scale ranging from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, induration/papulation, and oozing/crusting.

End point type	Secondary

End point timeframe:

Weeks 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, and 52

End point values	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID	LTS Period: Ruxolitinib 0.75% Cream BID	LTS Period: Ruxolitinib 1.5% Cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	187	203
Units: percentage of participants				
number (not applicable)				
Week 8	26.0	10.2	57.5	65.5
Week 12	59.6	45.8	59.6	73.0
Week 16	59.6	59.6	68.9	74.1
Week 20	69.0	58.7	71.1	74.5
Week 24	61.0	67.4	70.4	72.4
Week 28	67.6	67.4	74.1	72.0
Week 32	77.1	72.7	74.2	73.8
Week 36	81.3	69.8	73.3	79.3
Week 40	77.1	66.7	76.0	79.3
Week 44	74.3	70.5	75.2	80.1
Week 48	79.4	69.8	75.2	75.9
Week 52	79.4	74.4	76.7	80.1

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a ≥ 4-Point Improvement in Itch NRS Score From Baseline to Weeks 2 and 4

End point title	Percentage of Participants With a ≥ 4-Point Improvement in Itch NRS Score From Baseline to Weeks 2 and 4

End point description:

The Itch NRS is a daily participant-reported measure (24-hour recall), of the worst level of itch intensity using a ediary. Participants are asked to rate the itching severity because of their AD by selecting a number from 0 (no itch) to 10 (worst imaginable itch) that best describes their worst level of itching in the past 24 hours.

End point type	Secondary

End point timeframe:

Baseline to Weeks 2 and 4

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	80	157	146	
Units: percentage of participants				
number (not applicable)				
Week 2	5.0	27.4	32.2	
Week 4	12.5	38.2	45.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved EASI50 During the VC Period

End point title	Percentage of Participants Who Achieved EASI50 During the VC Period

End point description:

EASI scoring system examines 4 areas of the body (head/neck, trunk, upper limbs, and lower limbs) and weights them for participants of at least 8 years of age. Each of the 4 body regions is assessed separately for erythema (E), induration/papulation/edema (I), excoriations (Ex), and lichenification (l) each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe). Half scores are allowed between severities 1, 2 and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 and the severity strata are as follows: 0 = clear; 0.1 to 1.0 = almost clear; 1.1 to 7.0 = mild; 7.1 to 21.0 = moderate; 21.1 to 50.0 = severe; 50.1 to 72.0 = very severe. An EASI50 responder was defined as a participant achieving 50% or greater improvement from Baseline in EASI score.

End point type	Secondary

End point timeframe:

Baseline to Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: percentage of participants				
number (not applicable)				
Week 2	16.1	45.5	53.5	
Week 4	28.8	69.7	71.9	
Week 8	33.9	75.8	79.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved EASI75 at Weeks 2 and 4

End point title	Percentage of Participants Who Achieved EASI75 at Weeks 2 and 4

End point description:

EASI scoring system examines 4 areas of the body (head/neck, trunk, upper limbs, and lower limbs) and weights them for participants of at least 8 years of age. Each of the 4 body regions is assessed separately for erythema (E), induration/papulation/edema (I), excoriations (Ex), and lichenification (l) each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe). Half scores are allowed between severities 1, 2 and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 and the severity strata are as follows: 0 = clear; 0.1 to 1.0 = almost clear; 1.1 to 7.0 = mild; 7.1 to 21.0 = moderate; 21.1 to 50.0 = severe; 50.1 to 72.0 = very severe. An EASI75 responder was defined as a participant achieving 75% or greater improvement from Baseline in EASI score.

End point type	Secondary

End point timeframe:

Baseline to Weeks 2 and 4

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: percentage of participants				
number (not applicable)				
Week 2	4.2	25.5	31.6	
Week 4	10.2	42.0	50.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved EASI90 During the VC Period

End point title	Percentage of Participants Who Achieved EASI90 During the VC Period

End point description:

EASI scoring system examines 4 areas of the body (head/neck, trunk, upper limbs, and lower limbs) and weights them for participants of at least 8 years of age. Each of the 4 body regions is assessed separately for erythema (E), induration/papulation/edema (I), excoriations (Ex), and lichenification (l) each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe). Half scores are allowed between severities 1, 2 and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 and the severity strata are as follows: 0 = clear; 0.1 to 1.0 = almost clear; 1.1 to 7.0 = mild; 7.1 to 21.0 = moderate; 21.1 to 50.0 = severe; 50.1 to 72.0 = very severe. An EASI90 responder was defined as a participant achieving 90% or greater improvement from Baseline in EASI score.

End point type	Secondary

End point timeframe:

Baseline to Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: percentage of participants				
number (not applicable)				
Week 2	0.8	10.8	15.8	
Week 4	2.5	25.5	32.5	
Week 8	4.2	35.1	43.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in EASI Score During the VC Period

End point title	Percent Change From Baseline in EASI Score During the VC Period

End point description:

EASI scoring system examines 4 areas of the body (head/neck, trunk, upper limbs, and lower limbs) and weights them for participants of at least 8 years of age. Each of the 4 body regions is assessed separately for erythema (E), induration/papulation/edema (I), excoriations (Ex), and lichenification (I) each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe). Half scores are allowed between severities 1, 2 and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 and the severity strata are as follows: 0 = clear; 0.1 to 1.0 = almost clear; 1.1 to 7.0 = mild; 7.1 to 21.0 = moderate; 21.1 to 50.0 = severe; 50.1 to 72.0 = very severe. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: percent change				
least squares mean (standard error)				
Percent Change From Baseline at Week 2	-13.95 (± 4.02)	-45.86 (± 2.84)	-49.08 (± 2.86)	
Percent Change From Baseline at Week 4	-20.45 (± 3.62)	-65.00 (± 2.50)	-66.35 (± 2.51)	
Percent Change From Baseline at Week 8	-28.84 (± 3.57)	-73.37 (± 2.50)	-74.84 (± 2.46)	

Statistical analyses

Statistical analysis title	Mixed Model
Statistical analysis description: Percent change from Baseline in EASI score at Week 2	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-31.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-41.57
upper limit	-22.25
Variability estimate	Standard error of the mean
Dispersion value	4.92

Statistical analysis title	Mixed Model
Statistical analysis description: Percent change from Baseline in EASI score at Week 2	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-35.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.81
upper limit	-25.44
Variability estimate	Standard error of the mean
Dispersion value	4.93

Statistical analysis title	Mixed Model
Statistical analysis description: Percent change from Baseline in EASI score at Week 4	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-44.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-53.19
upper limit	-35.92
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Mixed Model
Statistical analysis description: Percent change from Baseline in EASI score at Week 4	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-45.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-54.55
upper limit	-37.26
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Mixed Model
Statistical analysis description: Percent change from Baseline in EASI score at Week 8	

Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-44.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-53.08
upper limit	-35.98
Variability estimate	Standard error of the mean
Dispersion value	4.35

Statistical analysis title	Mixed Model
Statistical analysis description:	
Percent change from Baseline in EASI score at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-54.51
upper limit	-37.48
Variability estimate	Standard error of the mean
Dispersion value	4.33

Secondary: Percent Change From Baseline in Scoring Atopic Dermatitis (SCORAD) Score During the VC Period

End point title	Percent Change From Baseline in Scoring Atopic Dermatitis (SCORAD) Score During the VC Period

End point description:

The SCORAD is a tool to assess extent and severity of eczema. To determine the extent, the rule of nines or handprint method is used to assess eczema affected area (A). To determine disease severity (B) it evaluates 6 clinical characteristics: 1. redness, 2. swelling, 3. oozing/crusting, 4. scratch marks, 5. lichenification, and 6. dryness on a 4-point scale of 0 to 3 (0=none, 1=mild, 2=moderate, 3=severe), added to give B with maximum score of 18. Subjective symptoms (C) of itch and sleeplessness are assessed using a visual analogue scale where 0 is no itch (or no sleeplessness) and 10 is the worst imaginable itch (or sleeplessness), added to give C with maximum score of 20. These 3 aspects: extent

of disease (A: 0-1-2), disease severity (B: 0-18), & subjective symptoms (C: 0-20) combined using A/5 + 7*B/2+ C to give a maximum possible score of 103, where 0 = no disease and 103 = severe disease. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: percent change				
arithmetic mean (standard deviation)				
Percent Change From Baseline at Week 2	-13.87 (± 24.816)	-39.62 (± 28.061)	-45.22 (± 28.461)	
Percent Change From Baseline at Week 4	-21.79 (± 30.083)	-54.85 (± 29.803)	-58.76 (± 29.580)	
Percent Change From Baseline at Week 8	-23.63 (± 33.918)	-63.71 (± 28.494)	-67.39 (± 29.098)	

Statistical analyses

Statistical analysis title	ANCOVA

Statistical analysis description:

Percent change from Baseline in SCORAD score at Week 8

Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-39.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.48
upper limit	-32.38
Variability estimate	Standard error of the mean
Dispersion value	3.59

Statistical analysis title	ANCOVA

Statistical analysis description:

Percent change from Baseline in SCORAD score at Week 8

Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-43.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-50.51
upper limit	-36.53
Variability estimate	Standard error of the mean
Dispersion value	3.56

Secondary: Change From Baseline in Itch NRS Score During the VC Period

End point title	Change From Baseline in Itch NRS Score During the VC Period

End point description:

The Itch NRS is a daily participant-reported measure (24-hour recall), of the worst level of itch intensity using a diary. Participants are asked to rate the itching severity because of their AD by selecting a number from 0 (no itch) to 10 (worst imaginable itch) that best describes their worst level of itching in the past 24 hours. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: units on a scale				
least squares mean (standard error)				
Change From Baseline at Week 2	-0.69 (± 0.21)	-2.21 (± 0.15)	-2.43 (± 0.15)	
Change From Baseline at Week 4	-1.03 (± 0.23)	-2.82 (± 0.17)	-3.00 (± 0.17)	
Change From Baseline at Week 8	-1.39 (± 0.25)	-3.28 (± 0.18)	-3.09 (± 0.17)	

Statistical analyses

Statistical analysis title	Mixed Model

Statistical analysis description:

Change from Baseline in Itch NRS score at Week 2

Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75%

	Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.02
upper limit	-1.01
Variability estimate	Standard error of the mean
Dispersion value	0.26

Statistical analysis title	Mixed Model
Statistical analysis description:	
Change from Baseline in Itch NRS score at Week 2	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.24
upper limit	-1.24
Variability estimate	Standard error of the mean
Dispersion value	0.26

Statistical analysis title	Mixed Model
Statistical analysis description:	
Change from Baseline in Itch NRS score at Week 4	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID

Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.36
upper limit	-1.23
Variability estimate	Standard error of the mean
Dispersion value	0.29

Statistical analysis title	Mixed Model
Statistical analysis description:	
Change from Baseline in Itch NRS score at Week 4	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.53
upper limit	-1.4
Variability estimate	Standard error of the mean
Dispersion value	0.29

Statistical analysis title	Mixed Model
Statistical analysis description:	
Change from Baseline in Itch NRS score at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.89

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.49
upper limit	-1.29
Variability estimate	Standard error of the mean
Dispersion value	0.31

Statistical analysis title	Mixed Model
Statistical analysis description:	
Change from Baseline in Itch NRS score at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	-1.1
Variability estimate	Standard error of the mean
Dispersion value	0.3

Secondary: Time to Achieve Itch NRS Score Improvement of at Least 2, 3 or 4 Points During the VC Period

End point title	Time to Achieve Itch NRS Score Improvement of at Least 2, 3 or 4 Points During the VC Period
End point description:	
The Itch NRS is a daily participant-reported measure (24-hour recall), of the worst level of itch intensity using a diary. Participants are asked to rate the itching severity because of their AD by selecting a number from 0 (no itch) to 10 (worst imaginable itch) that best describes their worst level of itching in the past 24 hours.	
End point type	Secondary
End point timeframe:	
Up to Week 8	

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: days				
median (confidence interval 95%)				
≥ 2-Point Improvement in Itch NRS Score	20.0 (13.0 to 24.0)	5.0 (4.0 to 6.0)	4.0 (4.0 to 5.0)	
≥ 3-Point Improvement in Itch NRS Score	44.0 (25.0 to 99999)	8.0 (6.0 to 13.0)	8.0 (6.0 to 11.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Skin Pain NRS Score During the VC Period

End point title	Change From Baseline in Skin Pain NRS Score During the VC Period

End point description:

The Skin Pain NRS is a daily patient-reported measure (24-hour recall), of the worst level of pain intensity from 0 (no pain) to 10 (worst imaginable pain) using a diary. Participants were asked, "Rate the pain severity from your atopic dermatitis skin changes by selecting a number that best describes your worst level of pain in the past 24 hours." A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: units on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2	-0.53 (± 1.677)	-1.78 (± 2.145)	-1.73 (± 2.125)	
Change From Baseline at Week 4	-0.93 (± 1.964)	-2.28 (± 2.449)	-2.27 (± 2.262)	
Change From Baseline at Week 8	-1.35 (± 2.540)	-2.45 (± 2.575)	-2.37 (± 2.428)	

Statistical analyses

Statistical analysis title	ANCOVA

Statistical analysis description:

Change from Baseline in Skin Pain NRS score at Week 8

Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.94
upper limit	-0.97
Variability estimate	Standard error of the mean
Dispersion value	0.25

Statistical analysis title	ANCOVA
Statistical analysis description:	
Change from Baseline in Skin Pain NRS score at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.72
upper limit	-0.76
Variability estimate	Standard error of the mean
Dispersion value	0.25

Secondary: Percentage of Participants With a Clinically Meaningful (≥ 6-Point) Improvement in the PROMIS Short Form – Sleep Disturbance (8b) 24-Hour Recall Score at Weeks 2, 4 and 8

End point title	Percentage of Participants With a Clinically Meaningful (≥ 6-Point) Improvement in the PROMIS Short Form – Sleep Disturbance (8b) 24-Hour Recall Score at Weeks 2, 4 and 8

End point description:

The PROMIS Short Form – Sleep Disturbance (8b) questionnaire assesses participant's self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep. This questionnaire is completed in the morning by the participant where each item asks the participant to rate the severity of the participant's sleep disturbance. It is a 5-point scale with a range in score from 8 to 40, with higher scores indicating greater severity of sleep disturbance.

End point type	Secondary
End point timeframe:	
Weeks 2 ,4 and 8	

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	110	213	211	
Units: percentage of participants				
number (not applicable)				
Week 2	10.0	14.6	18.0	
Week 4	12.7	16.9	18.0	
Week 8	19.1	20.7	25.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Participants With a Clinically Meaningful (≥ 6-Point) Improvement in the PROMIS Short Form – Sleep-Related Impairment (8a) 24-Hour Recall Score at Weeks 2, 4 and 8

End point title	Proportion of Participants With a Clinically Meaningful (≥ 6-Point) Improvement in the PROMIS Short Form – Sleep-Related Impairment (8a) 24-Hour Recall Score at Weeks 2, 4 and 8

End point description:

The PROMIS Short Form – Sleep-Related Impairment (8a) questionnaire assesses participant's self-reported perceptions of alertness, sleepiness, and tiredness during usual waking hours and the perceived functional impairments during wakefulness associated with sleep problems or impaired alertness. The questionnaire is filled in the evening where each item asks the participant to rate the severity of the participant's sleep impairment. It has 8 simple questions with a 5-point scale with a range in score from 8 to 40, with higher scores indicating greater severity of sleep-related impairment.

End point type	Secondary
End point timeframe:	
Weeks 2, 4 and 8	

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	111	215	212	
Units: percentage of participants				
number (not applicable)				
Week 2	7.2	10.7	13.2	
Week 4	9.0	13.0	19.8	
Week 8	13.5	20.0	23.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PROMIS Short Form – Sleep Disturbance (8b) 24-Hour Recall Score During the VC Period

End point title	Change From Baseline in PROMIS Short Form – Sleep Disturbance (8b) 24-Hour Recall Score During the VC Period

End point description:

The PROMIS Short Form – Sleep Disturbance (8b) questionnaire assesses participant's self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep. This questionnaire is completed in the morning by the participant where each item asks the participant to rate the severity of the participant's sleep disturbance. It is a 5-point scale with a range in score from 8 to 40, with higher scores indicating greater severity of sleep disturbance. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: units on a scale				
least squares mean (standard error)				
Change From Baseline at Week 2	-1.32 (± 0.46)	-1.92 (± 0.33)	-2.30 (± 0.33)	
Change From Baseline at Week 4	-2.02 (± 0.50)	-2.32 (± 0.35)	-2.88 (± 0.35)	
Change From Baseline at Week 8	-2.60 (± 0.60)	-3.30 (± 0.42)	-3.40 (± 0.41)	

Statistical analyses

Statistical analysis title	Mixed Model

Statistical analysis description:

Change from Baseline in PROMIS Short Form–Sleep Disturbance (8b) 24-hour recall score at Week 2

Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID

Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2903
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.71
upper limit	0.51
Variability estimate	Standard error of the mean
Dispersion value	0.57

Statistical analysis title	Mixed Model
Statistical analysis description:	
Change from Baseline in PROMIS Short Form–Sleep Disturbance (8b) 24-hour recall score at Week 2	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0837
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.09
upper limit	0.13
Variability estimate	Standard error of the mean
Dispersion value	0.57

Statistical analysis title	Mixed Model
Statistical analysis description:	
Change from Baseline in PROMIS Short Form–Sleep Disturbance (8b) 24-hour recall score at Week 4	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6272
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	0.91
Variability estimate	Standard error of the mean
Dispersion value	0.61

Statistical analysis title	Mixed Model
Statistical analysis description:	
Change from Baseline in PROMIS Short Form–Sleep Disturbance (8b) 24-hour recall score at Week 4	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1609
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.07
upper limit	0.34
Variability estimate	Standard error of the mean
Dispersion value	0.61

Statistical analysis title	Mixed Model
Statistical analysis description:	
Change from Baseline in PROMIS Short Form–Sleep Disturbance (8b) 24-hour recall score at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3362
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.13
upper limit	0.73
Variability estimate	Standard error of the mean
Dispersion value	0.73

Statistical analysis title	Mixed Model
Statistical analysis description: Change from Baseline in PROMIS Short Form–Sleep Disturbance (8b) 24-hour recall score at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.269
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.23
upper limit	0.62
Variability estimate	Standard error of the mean
Dispersion value	0.73

Secondary: Change From Baseline in PROMIS Short Form – Sleep-Related Impairment (8a) 24-Hour Recall Score During the VC Period

End point title	Change From Baseline in PROMIS Short Form – Sleep-Related Impairment (8a) 24-Hour Recall Score During the VC Period

End point description:

The PROMIS Short Form – Sleep-Related Impairment (8a) questionnaire assesses participant's self-reported perceptions of alertness, sleepiness, and tiredness during usual waking hours and the perceived functional impairments during wakefulness associated with sleep problems or impaired alertness. The questionnaire is filled in the evening where each item asks the participant to rate the severity of the participant's sleep impairment. It has 8 simple questions with a 5-point scale with a range in score from 8 to 40, with higher scores indicating greater severity of sleep-related impairment. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: units on a scale				
least squares mean (standard error)				
Change From Baseline at Week 2	-0.80 (± 0.44)	-1.87 (± 0.31)	-2.00 (± 0.31)	
Change From Baseline at Week 4	-1.37 (± 0.49)	-2.13 (± 0.35)	-2.91 (± 0.35)	

Change From Baseline at Week 8	-2.08 (± 0.55)	-3.26 (± 0.39)	-3.31 (± 0.38)	

Statistical analyses

Statistical analysis title	Mixed Model
Statistical analysis description:	
Change from Baseline in PROMIS Short Form – Sleep-Related Impairment (8a) 24-hour recall score at Week 2	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0482
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.13
upper limit	-0.01
Variability estimate	Standard error of the mean
Dispersion value	0.54

Statistical analysis title	Mixed Model
Statistical analysis description:	
Change from Baseline in PROMIS Short Form – Sleep-Related Impairment (8a) 24-hour recall score at Week 2	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0271
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.26
upper limit	-0.14
Variability estimate	Standard error of the mean
Dispersion value	0.54

Statistical analysis title	Mixed Model
Statistical analysis description: Change from Baseline in PROMIS Short Form – Sleep-Related Impairment (8a) 24-hour recall score at Week 4	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2091
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.94
upper limit	0.42
Variability estimate	Standard error of the mean
Dispersion value	0.6

Statistical analysis title	Mixed Model
Statistical analysis description: Change from Baseline in PROMIS Short Form – Sleep-Related Impairment (8a) 24-hour recall score at Week 4	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0111
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.71
upper limit	-0.35
Variability estimate	Standard error of the mean
Dispersion value	0.6

Statistical analysis title	Mixed Model

Statistical analysis description:

Change from Baseline in PROMIS Short Form – Sleep-Related Impairment (8a) 24-hour recall score at Week 8

Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0802
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.51
upper limit	0.14
Variability estimate	Standard error of the mean
Dispersion value	0.68

Statistical analysis title	Mixed Model

Statistical analysis description:

Change from Baseline in PROMIS Short Form – Sleep-Related Impairment (8a) 24-hour recall score at Week 8

Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0666
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.56
upper limit	0.09
Variability estimate	Standard error of the mean
Dispersion value	0.67

Secondary: Change From Baseline in PROMIS Short Form – Sleep-Related Impairment (8a) 7-Day Recall Score During the LTS Period

End point title	Change From Baseline in PROMIS Short Form – Sleep-Related Impairment (8a) 7-Day Recall Score During the LTS Period

End point description:

The PROMIS Short Form – Sleep-Related Impairment (8a) questionnaire assesses participant's self-reported perceptions of alertness, sleepiness, and tiredness during usual waking hours and the perceived functional impairments during wakefulness associated with sleep problems or impaired

alertness. The questionnaire is filled in the evening where each item asks the participant to rate the severity of the participant's sleep impairment. It has 8 simple questions with a 5-point scale with a range in score from 8 to 40, with higher scores indicating greater severity of sleep-related impairment. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 24, and 52

End point values	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID	LTS Period: Ruxolitinib 0.75% Cream BID	LTS Period: Ruxolitinib 1.5% Cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	46	171	180
Units: units on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 12	-1.73 (± 4.019)	-2.04 (± 6.282)	-0.32 (± 4.724)	-0.04 (± 3.914)
Change From Baseline at Week 24	-0.47 (± 4.695)	-1.04 (± 5.969)	-0.11 (± 5.136)	0.22 (± 4.868)
Change From Baseline at Week 52	-1.48 (± 5.304)	-2.33 (± 6.582)	-0.24 (± 5.660)	-0.69 (± 5.483)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PROMIS Short Form – Sleep Disturbance (8b) 7-Day Recall Score During the LTS Period

End point title	Change From Baseline in PROMIS Short Form – Sleep Disturbance (8b) 7-Day Recall Score During the LTS Period

End point description:

The PROMIS Short Form – Sleep Disturbance (8b) questionnaire assesses participant's self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep. This questionnaire is completed in the morning by the participant where each item asks the participant to rate the severity of the participant's sleep disturbance. It is a 5-point scale with a range in score from 8 to 40, with higher scores indicating greater severity of sleep disturbance. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 24, and 52

End point values	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID	LTS Period: Ruxolitinib 0.75% Cream BID	LTS Period: Ruxolitinib 1.5% Cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	46	171	180
Units: units on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 12	-2.00 (± 4.973)	-1.80 (± 5.588)	-0.37 (± 4.621)	-0.32 (± 4.466)
Change From Baseline at Week 24	-0.97 (± 6.188)	-1.87 (± 5.691)	-0.03 (± 4.688)	0.06 (± 5.376)
Change From Baseline at Week 52	-1.39 (± 7.198)	-2.88 (± 7.235)	-0.36 (± 6.049)	-0.42 (± 5.950)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Atopic Dermatitis Afflicted Percentage of Body Surface Area (%BSA) During the VC Period

End point title	Change From Baseline in Atopic Dermatitis Afflicted Percentage of Body Surface Area (%BSA) During the VC Period

End point description:

Body surface area affected by AD was assessed for 4 separate body regions and is collected as part of the EASI assessment: head and neck, trunk (including genital region), upper extremities, and lower extremities (including the buttocks). Each body region was assessed for disease extent ranging from 0% to 100% involvement. The overall total percentage was reported based off of all 4 body regions combined, after applying specific multipliers to the different body regions to account for the percent of the total BSA represented by each of the 4 regions. Use the percentage of skin affected for each region (0 to 100%) in EASI as follows: BSA Total = 0.1*BSA head and neck + 0.3*BSA trunk + 0.2* BSA upper limbs + 0.4*BSA lower limbs. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: units on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2	-0.48 (± 3.008)	-2.92 (± 3.944)	-3.99 (± 4.636)	
Change From Baseline at Week 4	-1.62 (± 3.338)	-4.77 (± 4.711)	-5.45 (± 5.223)	
Change From Baseline at Week 8	-2.13 (± 4.671)	-6.00 (± 4.845)	-6.61 (± 5.479)	

Statistical analyses

Statistical analysis title	ANCOVA
Statistical analysis description: Change from Baseline in %BSA at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.84
upper limit	-2.97
Variability estimate	Standard error of the mean
Dispersion value	0.48

Statistical analysis title	ANCOVA
Statistical analysis description: Change from Baseline in %BSA at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.47
upper limit	-3.63
Variability estimate	Standard error of the mean
Dispersion value	0.47

Secondary: Change From Baseline in Atopic Dermatitis Afflicted %BSA During the LTS Period

End point title	Change From Baseline in Atopic Dermatitis Afflicted %BSA During the LTS Period

End point description:

Body surface area affected by AD was assessed for 4 separate body regions and is collected as part of the EASI assessment: head and neck, trunk (including genital region), upper extremities, and lower extremities (including the buttocks). Each body region was assessed for disease extent ranging from 0% to 100% involvement. The overall total percentage was reported based off of all 4 body regions combined, after applying specific multipliers to the different body regions to account for the percent of the total BSA represented by each of the 4 regions. Use the percentage of skin affected for each region (0 to 100%) in EASI as follows: BSA Total = 0.1*BSA head and neck + 0.3*BSA trunk + 0.2* BSA upper limbs + 0.4*BSA lower limbs. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52

End point values	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID	LTS Period: Ruxolitinib 0.75% Cream BID	LTS Period: Ruxolitinib 1.5% Cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	187	203
Units: units on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 12	-3.89 (± 5.530)	-4.71 (± 4.980)	-6.61 (± 4.395)	-7.69 (± 5.106)
Change From Baseline at Week 16	-4.41 (± 5.553)	-5.47 (± 5.289)	-6.77 (± 5.270)	-7.80 (± 5.096)
Change From Baseline at Week 20	-4.88 (± 5.210)	-6.27 (± 6.193)	-7.48 (± 4.900)	-8.05 (± 4.920)
Change From Baseline at Week 24	-4.70 (± 4.775)	-6.37 (± 5.817)	-7.49 (± 4.988)	-8.00 (± 5.071)
Change From Baseline at Week 28	-4.59 (± 4.677)	-6.21 (± 6.597)	-7.48 (± 4.827)	-8.07 (± 5.099)
Change From Baseline at Week 32	-5.10 (± 5.203)	-6.79 (± 5.960)	-7.69 (± 4.891)	-7.89 (± 5.004)
Change From Baseline at Week 36	-4.65 (± 5.266)	-6.16 (± 6.045)	-7.79 (± 4.856)	-8.38 (± 5.119)
Change From Baseline at Week 40	-4.59 (± 5.196)	-6.42 (± 5.887)	-7.83 (± 4.976)	-8.44 (± 5.090)
Change From Baseline at Week 44	-5.18 (± 4.901)	-6.56 (± 6.200)	-7.92 (± 5.082)	-8.43 (± 5.122)
Change From Baseline at Week 48	-5.30 (± 5.130)	-6.61 (± 5.897)	-7.64 (± 5.380)	-8.33 (± 5.204)
Change From Baseline at Week 52	-5.12 (± 5.114)	-6.83 (± 5.837)	-7.92 (± 4.823)	-8.42 (± 4.973)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient-Oriented Eczema Measure (POEM) Score During the VC Period

End point title	Change From Baseline in Patient-Oriented Eczema Measure (POEM) Score During the VC Period

End point description:

The POEM is a 7-question quality-of-life assessment that asks how many days the participant has been bothered by various aspects of their skin condition during the past 7 days. It assesses disease symptoms (dryness, itching, flaking, cracking, sleep loss, bleeding and weeping) on a scale ranging from 0-4 (0 = no days, 1 = 1-2 days, 2 = 3-4 days, 3 = 5-6 days, 4 = everyday). The sum of the 7 items gives the total POEM score of 0 (absent disease) to 28 (severe disease). High scores are indicative of more severe disease and poor quality of life. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: units on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2	-2.06 (± 5.371)	-8.21 (± 6.694)	-8.86 (± 6.807)	
Change From Baseline at Week 4	-4.01 (± 6.125)	-9.59 (± 6.883)	-9.97 (± 6.839)	
Change From Baseline at Week 8	-4.18 (± 6.574)	-10.34 (± 6.835)	-10.08 (± 7.167)	

Statistical analyses

Statistical analysis title	ANCOVA

Statistical analysis description:

Change from Baseline in POEM score at Week 8

Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-6.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.38
upper limit	-4.86
Variability estimate	Standard error of the mean
Dispersion value	0.64

Statistical analysis title	ANCOVA
Statistical analysis description:	
Change from Baseline in POEM score at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.17
upper limit	-4.67
Variability estimate	Standard error of the mean
Dispersion value	0.64

Secondary: Change From Baseline in POEM Score During the LTS Period

End point title	Change From Baseline in POEM Score During the LTS Period

End point description:

The POEM is a 7-question quality-of-life assessment that asks how many days the participant has been bothered by various aspects of their skin condition during the past 7 days. It assesses disease symptoms (dryness, itching, flaking, cracking, sleep loss, bleeding and weeping) on a scale ranging from 0-4 (0 = no days, 1 = 1-2 days, 2 = 3-4 days, 3 = 5-6 days, 4 = everyday). The sum of the 7 items gives the total POEM score of 0 (absent disease) to 28 (severe disease). High scores are indicative of more severe disease and poor quality of life. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 24 and 52

End point values	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID	LTS Period: Ruxolitinib 0.75% Cream BID	LTS Period: Ruxolitinib 1.5% Cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	187	203
Units: units on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 12	-5.65 (± 7.460)	-6.04 (± 7.269)	-9.72 (± 6.571)	-10.58 (± 6.883)
Change From Baseline at Week 24	-4.03 (± 7.006)	-5.71 (± 6.567)	-10.30 (± 6.675)	-10.58 (± 6.848)
Change From Baseline at Week 52	-6.15 (± 7.304)	-6.28 (± 7.340)	-10.29 (± 6.187)	-10.65 (± 6.699)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dermatology Life Quality Index (DLQI) Score During the VC Period

End point title	Change From Baseline in Dermatology Life Quality Index (DLQI) Score During the VC Period

End point description:

The DLQI is a simple, 10 question (Q) validated quality-of-life questionnaire to measure how much the skin problem has affected the participant. It covers 6 domains including symptoms and feelings (Q1 and Q2), daily activities (Q3 and Q4), leisure (Q5 and Q6), work and school (Q7), personal relationships (Q8 and Q9), and treatment(Q10). The recall Period of this scale is over the last week. Response categories include 0-not at all, 1-a little, 2-a lot, and 3-very much, and unanswered or not relevant responses scored as 0. Scores range from 0 ("no impact on participant's life") to 30 ("extremely large effect on participant's life"), and a 4-point change from Baseline is considered as the minimal clinically important difference threshold. A negative change from Baseline indicates less impact of the skin problem on participant's life.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4, and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	105	194	202	
Units: units on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2	-0.91 (± 4.679)	-5.40 (± 5.874)	-5.14 (± 5.394)	
Change From Baseline at Week 4	-3.00 (± 4.962)	-6.62 (± 5.966)	-6.16 (± 5.771)	
Change From Baseline at Week 8	-3.30 (± 5.353)	-7.18 (± 6.004)	-6.41 (± 5.731)	

Statistical analyses

Statistical analysis title	ANCOVA
Statistical analysis description: Change from Baseline in total DLQI score at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.19
upper limit	-2.32
Variability estimate	Standard error of the mean
Dispersion value	0.48

Statistical analysis title	ANCOVA
Statistical analysis description: Change from Baseline in total DLQI score at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	307
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.67
upper limit	-1.83
Variability estimate	Standard error of the mean
Dispersion value	0.47

Secondary: Change From Baseline in DLQI Score During the LTS Period

End point title	Change From Baseline in DLQI Score During the LTS Period

End point description:

The DLQI is a simple, 10 question (Q) validated quality-of-life questionnaire to measure how much the skin problem has affected the participant. It covers 6 domains including symptoms and feelings (Q1 and Q2), daily activities (Q3 and Q4), leisure (Q5 and Q6), work and school (Q7), personal relationships (Q8 and Q9), and treatment(Q10). The recall Period of this scale is over the last week. Response categories include 0-not at all, 1-a little, 2-a lot, and 3-very much, and unanswered or not relevant responses scored as 0. Scores range from 0 ("no impact on participant's life") to 30 ("extremely large effect on participant's life"), and a 4-point change from Baseline is considered as the minimal clinically important difference threshold. A negative change from Baseline indicates less impact of the skin problem on participant's life.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 24, and 52

End point values	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID	LTS Period: Ruxolitinib 0.75% Cream BID	LTS Period: Ruxolitinib 1.5% Cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	41	157	180
Units: units on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 12	-2.09 (± 3.611)	-2.79 (± 5.542)	-7.07 (± 5.931)	-7.06 (± 6.044)
Change From Baseline at Week 24	-1.22 (± 3.293)	-3.08 (± 3.759)	-7.17 (± 6.152)	-7.01 (± 5.754)
Change From Baseline at Week 52	-3.09 (± 3.753)	-3.20 (± 4.234)	-7.49 (± 5.776)	-7.28 (± 6.196)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Children Dermatology Life Quality Index (CDLQI) Score During the VC Period

End point title	Change from Baseline in Children Dermatology Life Quality Index (CDLQI) Score During the VC Period

End point description:

CDLQI is the youth/children’s version of the DLQI. The CDLQI is a simple 10 question (Q) validated quality-of-life questionnaire. It covers 6 domains including symptoms and feelings (Q1 and Q2), leisure (Q4, Q5, and Q6), school or holidays (Q7), personal relationships (Q3 and Q8), sleep (Q9) and treatment (Q10). Response categories include 0-not at all, 1-a little, 2-a lot, and 3-very much, and unanswered or not relevant responses scored as 0. The total DLQI score is calculated by adding the score of each question resulting in a maximum score of 30 (extremely large effect on participant's life) and a minimum score of 0 (no impact on participant's life) and a 4-point change from Baseline is considered as the minimal clinically important difference threshold. A negative change from Baseline indicates less impact of the skin problem on participant's life.

End point type	Secondary
End point timeframe:	
Baseline, Weeks 2, 4, and 8	

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	37	26	
Units: units on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2	-1.67 (± 5.416)	-3.45 (± 4.570)	-3.58 (± 4.032)	
Change From Baseline at Week 4	-3.10 (± 6.488)	-4.82 (± 4.934)	-4.52 (± 5.221)	
Change From Baseline at Week 8	-2.36 (± 7.500)	-4.56 (± 5.061)	-4.12 (± 6.418)	

Statistical analyses

Statistical analysis title	ANCOVA
Statistical analysis description:	
Change from Baseline in total CDLQI score at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0099
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.24
upper limit	-1.03
Variability estimate	Standard error of the mean
Dispersion value	1.55

Statistical analysis title	ANCOVA
Statistical analysis description:	
Change from Baseline in total CDLQI score at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID

Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0542
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	0.06
Variability estimate	Standard error of the mean
Dispersion value	1.59

Secondary: Change from Baseline in CDLQI Score During the LTS Period

End point title	Change from Baseline in CDLQI Score During the LTS Period

End point description:

CDLQI is the youth/children's version of the DLQI. The CDLQI is a simple 10 question (Q) validated quality-of-life questionnaire. It covers 6 domains including symptoms and feelings (Q1 and Q2), leisure (Q4, Q5, and Q6), school or holidays (Q7), personal relationships (Q3 and Q8), sleep (Q9) and treatment (Q10). Response categories include 0-not at all, 1-a little, 2-a lot, and 3-very much, and unanswered or not relevant responses scored as 0. The total DLQI score is calculated by adding the score of each question resulting in a maximum score of 30 (extremely large effect on participant's life) and a minimum score of 0 (no impact on participant's life) and a 4-point change from Baseline is considered as the minimal clinically important difference threshold. A negative change from Baseline indicates less impact of the skin problem on participant's life.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 24, and 52

End point values	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID	LTS Period: Ruxolitinib 0.75% Cream BID	LTS Period: Ruxolitinib 1.5% Cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	30	23
Units: units on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 12	-7.50 (± 2.121)	-4.88 (± 5.436)	-5.54 (± 5.153)	-5.57 (± 5.482)
Change From Baseline at Week 24	-8.50 (± 2.121)	-4.88 (± 4.549)	-5.72 (± 6.066)	-5.68 (± 7.326)
Change From Baseline at Week 52	-8.00 (± 1.414)	-6.38 (± 9.023)	-5.35 (± 4.902)	-6.57 (± 5.983)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Patient Global Impression of Change (PGIC) Score at Weeks 2, 4, and 8

End point title	Mean Patient Global Impression of Change (PGIC) Score at Weeks 2, 4, and 8

End point description:

The PGIC is a participants' self-reporting measure that reflects their belief about the efficacy of treatment. It is a 7-point scale where participants rate the questions as: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, and 7=very much worse. The lower score indicates improvement.

End point type	Secondary

End point timeframe:

Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 2	3.32 (± 1.268)	2.19 (± 1.019)	1.95 (± 0.980)	
Week 4	2.99 (± 1.259)	1.95 (± 0.980)	1.71 (± 0.852)	
Week 8	2.93 (± 1.380)	1.73 (± 0.906)	1.70 (± 0.909)	

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Participants With Each Score on the PGIC at Weeks 2, 4, and 8

End point title	Proportion of Participants With Each Score on the PGIC at Weeks 2, 4, and 8

End point description:

The PGIC is a participants' self-reporting measure that reflects their belief about the efficacy of treatment. It is a 7-point scale where participants rate the questions as: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, and 7=very much worse. The lower score indicates improvement.

End point type	Secondary

End point timeframe:

Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: percentage of participants				
number (not applicable)				
Week 2 - Very Much Improved: 1	4.6	32.1	41.0	
Week 2 - Much Improved: 2	20.2	27.1	30.9	
Week 2 - Minimally Improved: 3	38.5	32.1	20.7	
Week 2 - No Change: 4	21.1	7.8	6.5	
Week 2 - Minimally Worse: 5	7.3	0.5	0.9	
Week 2 - Much Worse: 6	7.3	0.5	0.0	
Week 2 - Very Much Worse: 7	0.9	0.0	0.0	
Week 4 - Very Much Improved: 1	10.0	41.9	49.1	
Week 4 - Much Improved: 2	29.0	28.6	35.2	
Week 4 - Minimally Improved: 3	29.0	22.1	12.0	
Week 4 - No Change: 4	20.0	6.9	2.8	
Week 4 - Minimally Worse: 5	8.0	0.5	0.9	
Week 4 - Much Worse: 6	4.0	0.0	0.0	
Week 4 - Very Much Worse: 7	0.0	0.0	0.0	
Week 8 - Very Much Improved: 1	16.8	52.7	51.6	
Week 8 - Much Improved: 2	24.8	26.1	32.6	
Week 8 - Minimally Improved: 3	23.8	16.3	12.1	
Week 8 - No Change: 4	22.8	4.9	1.9	
Week 8 - Minimally Worse: 5	7.9	0.0	1.4	
Week 8 - Much Worse: 6	3.0	0.0	0.5	
Week 8 - Very Much Worse: 7	1.0	0.0	0.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Participants With a Score of Either 1 or 2 on the PGIC at Weeks 2, 4, and 8

End point title	Proportion of Participants With a Score of Either 1 or 2 on the PGIC at Weeks 2, 4, and 8

End point description:

The PGIC is a participants' self-reporting measure that reflects their belief about the efficacy of treatment. It is a 7-point scale where participants rate the questions as: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, and 7=very much worse. The lower score indicates improvement.

End point type	Secondary

End point timeframe:

Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: percentage of participants				
number (confidence interval 95%)				
Week 2	24.8 (17.0 to 34.0)	59.2 (52.3 to 65.8)	71.9 (65.4 to 77.8)	
Week 4	39.0 (29.4 to 49.3)	70.5 (64.0 to 76.5)	84.3 (78.7 to 88.8)	
Week 8	41.6 (31.9 to 51.8)	78.8 (72.5 to 84.2)	84.2 (78.6 to 88.8)	

Statistical analyses

Statistical analysis title	Exact Logistic regression
Statistical analysis description: Percentage of participants with a score of either 1 or 2 on the PGIC at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Conditional Exact Test
Parameter estimate	Odds ratio (OR)
Point estimate	5.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.987
upper limit	9.049

Statistical analysis title	Exact Logistic regression
Statistical analysis description: Percentage of participants with a score of either 1 or 2 on the PGIC at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Conditional Exact Test
Parameter estimate	Odds ratio (OR)
Point estimate	7.47

Confidence interval	
level	95 %
sides	2-sided
lower limit	4.23
upper limit	13.415

Secondary: Change From Baseline in EuroQuality of Life Five Dimensions (EQ-5D-5L) Visual Analogue Scale (VAS) Score During the VC Period

End point title	Change From Baseline in EuroQuality of Life Five Dimensions (EQ-5D-5L) Visual Analogue Scale (VAS) Score During the VC Period

End point description:

EQ-5D-5L questionnaire has: EQ-5D-5L descriptive system & EQ-VAS. EQ-5D is a validated, self-administered, generic utility questionnaire wherein participants rate their current health state based on 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. 5L indicates that for each dimension, there are 5 levels:1=no problems,2=slight problems,3=moderate problems,4=severe problems, and 5=extreme problems. EQ-5D-5L score is assessed using VAS that ranges from 0 to 100 millimetres (mm), where 0 indicates "worst health you can imagine" and 100 indicates "best health you can imagine". The participant was asked to indicate his/her health state over past 7 days in each of the 5 dimensions. Digits for the 5 dimensions can be combined into a 5-digit number that describes the participant's health state. In the EQ-VAS, participants had to record their health state on a scale ranging from 0 to 100. A positive change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4 and 8

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: units on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2	1.43 (± 13.975)	6.16 (± 14.409)	6.98 (± 15.956)	
Change From Baseline at Week 4	3.31 (± 15.061)	6.38 (± 17.512)	8.55 (± 17.244)	
Change From Baseline at Week 8	2.97 (± 15.946)	7.16 (± 18.245)	8.36 (± 16.767)	

Statistical analyses

Statistical analysis title	ANCOVA

Statistical analysis description:

Change from Baseline in EQ VAS score at Week 8

Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID

Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0044
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	5.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.59
upper limit	8.54
Variability estimate	Standard error of the mean
Dispersion value	1.77

Statistical analysis title	ANCOVA
Statistical analysis description:	
Change from Baseline in EQ VAS score at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.015
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	4.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	7.86
Variability estimate	Standard error of the mean
Dispersion value	1.78

Secondary: Change From Baseline in Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI-SHP) Version 2.0 (v2.0) During the VC Period

End point title	Change From Baseline in Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI-SHP) Version 2.0 (v2.0) During the VC Period

End point description:

The WPAI-SHP is a 6-item participant questionnaire developed to measure the effect of overall health and specific symptoms on productivity at work and regular activities outside of it in the past 7 days. The WPAI-SHP consists of 6 questions as follows: 1=currently employed; 2=hours missed due to AD; 3=hours missed other reasons; 4=hours actually worked; 5=degree AD affected productivity while working; 6=degree AD affected regular activities and the computed percentage, range for each sub scale is from 0 to 100, with higher values indicating greater impairment and less productivity. A negative change from Baseline indicates improvement.

End point type	Secondary
End point timeframe: Baseline, Weeks 2, 4, and 8	

End point values	VC Period: Vehicle Cream BID	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	231	228	
Units: units on a scale				
arithmetic mean (standard deviation)				
% Work Missed : Change From Baseline at Week 2	4.77 (± 23.348)	0.64 (± 19.190)	2.53 (± 17.803)	
% Work Missed :Change From Baseline at Week 4	3.22 (± 22.497)	-0.15 (± 22.299)	4.31 (± 19.679)	
% Work Missed :: Change From Baseline at Week 8	10.03 (± 24.477)	3.50 (± 24.760)	3.51 (± 18.479)	
% Impairment While Working : Baseline at Week 2	-4.49 (± 25.500)	-12.76 (± 21.371)	-13.24 (± 19.958)	
% Impairment While Working: Baseline at Week 4	-12.05 (± 24.514)	-15.25 (± 22.648)	-18.10 (± 19.832)	
% Impairment While Working: Baseline at Week 8	-10.93 (± 25.618)	-18.83 (± 23.365)	-17.32 (± 19.013)	
% Overall Work Impairment: Baseline at Week 2	-2.78 (± 31.057)	-12.58 (± 24.670)	-11.10 (± 23.717)	
% Overall Work Impairment: Baseline at Week 4	-10.41 (± 26.627)	-15.14 (± 25.543)	-16.19 (± 22.037)	
% Overall Work Impairment:: Baseline at Week 8	-2.06 (± 29.625)	-17.00 (± 25.916)	-13.65 (± 22.476)	
% Activity Impairment : Baseline at Week 2	-4.63 (± 21.243)	-12.79 (± 23.462)	-16.68 (± 23.295)	
% Activity Impairment : Baseline at Week 4	-8.38 (± 20.981)	-17.24 (± 24.715)	-18.70 (± 23.550)	
% Activity Impairment : Baseline at Week 8	-9.50 (± 25.361)	-19.66 (± 25.157)	-18.60 (± 25.557)	

Statistical analyses

Statistical analysis title	ANCOVA
Statistical analysis description: Percent work time missed due to AD: Change from Baseline in WPAI-SHP v2.0 at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.142
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-5.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.12
upper limit	1.89
Variability estimate	Standard error of the mean
Dispersion value	3.81

Statistical analysis title	ANCOVA
Statistical analysis description:	
Percent work time missed due to AD: Change from Baseline in WPAI-SHP v2.0 at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0375
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.51
upper limit	-0.47
Variability estimate	Standard error of the mean
Dispersion value	3.82

Statistical analysis title	ANCOVA
Statistical analysis description:	
Percent impairment while working due to AD: Change from Baseline in WPAI-SHP v2.0 at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0012
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-9.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.48
upper limit	-3.63
Variability estimate	Standard error of the mean
Dispersion value	2.75

Statistical analysis title	ANCOVA
Statistical analysis description: Percent impairment while working due to AD: Change from Baseline in WPAI-SHP v2.0 at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0095
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-7.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.58
upper limit	-1.77
Variability estimate	Standard error of the mean
Dispersion value	2.74

Statistical analysis title	ANCOVA
Statistical analysis description: Percent overall work impairment due to AD: Change from Baseline in WPAI-SHP v2.0 at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-15.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.69
upper limit	-7.73
Variability estimate	Standard error of the mean
Dispersion value	3.8

Statistical analysis title	ANCOVA
Statistical analysis description: Percent overall work impairment due to AD: Change from Baseline in WPAI-SHP v2.0 at Week 8	

Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-12.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.1
upper limit	-5.18
Variability estimate	Standard error of the mean
Dispersion value	3.79

Statistical analysis title	ANCOVA
Statistical analysis description:	
Percent activity impairment due to AD: Change from Baseline in WPAI-SHP v2.0 at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-12.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.18
upper limit	-7.95
Variability estimate	Standard error of the mean
Dispersion value	2.09

Statistical analysis title	ANCOVA
Statistical analysis description:	
Percent activity impairment due to AD: Change from Baseline in WPAI-SHP v2.0 at Week 8	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID

Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-10.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.53
upper limit	-6.37
Variability estimate	Standard error of the mean
Dispersion value	2.08

Secondary: Change From Baseline in WPAI-SHP v2.0 During the LTS Period

End point title	Change From Baseline in WPAI-SHP v2.0 During the LTS Period

End point description:

The WPAI-SHP is a 6-item participant questionnaire developed to measure the effect of overall health and specific symptoms on productivity at work and regular activities outside of it in the past 7 days. The WPAI-SHP consists of 6 questions as follows: 1=currently employed; 2=hours missed due to AD; 3=hours missed other reasons; 4=hours actually worked; 5=degree AD affected productivity while working; 6=degree AD affected regular activities and the computed percentage, range for each sub scale is from 0 to 100, with higher values indicating greater impairment and less productivity. A negative change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 24, 36, and 52

End point values	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID	LTS Period: Ruxolitinib 0.75% Cream BID	LTS Period: Ruxolitinib 1.5% Cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	49	187	203
Units: units on a scale				
arithmetic mean (standard deviation)				
%Work Time Missed Baseline to Week 12	-4.26 (± 24.958)	-0.81 (± 17.257)	-0.17 (± 24.581)	3.48 (± 16.470)
%Work Time Missed Baseline to Week 24	-2.06 (± 28.778)	-11.35 (± 22.947)	-0.38 (± 23.511)	5.13 (± 24.419)
%Work Time Missed Baseline to Week 36	-1.04 (± 23.312)	-5.44 (± 27.625)	-0.02 (± 20.410)	3.37 (± 20.967)
%Work Time Missed Baseline to Week 52	-2.29 (± 25.148)	3.60 (± 24.186)	0.50 (± 28.348)	6.36 (± 21.806)
% Impairment While Working Baseline to Week 12	-5.91 (± 10.075)	-13.50 (± 29.784)	-19.87 (± 21.572)	-22.02 (± 19.652)
% Impairment While Working Baseline to Week 24	-7.14 (± 22.835)	-16.47 (± 18.007)	-19.74 (± 23.719)	-22.56 (± 22.433)

% Impairment While Working Baseline to Week 36	-7.33 (± 15.337)	-11.43 (± 21.432)	-18.79 (± 21.232)	-24.61 (± 20.359)
% Impairment While Working Baseline to Week 52	-16.00 (± 24.129)	-13.85 (± 17.578)	-20.00 (± 25.312)	-21.86 (± 25.836)
% Overall Work Impairment : Baseline tp Week 12	-11.64 (± 20.194)	-10.72 (± 23.285)	-17.40 (± 23.123)	-17.91 (± 24.692)
% Overall Work Impairment : Baseline tp Week 24	-10.99 (± 33.070)	-25.22 (± 25.009)	-17.83 (± 27.226)	-19.31 (± 26.893)
% Overall Work Impairment : Baseline tp Week 36	-7.77 (± 25.443)	-15.27 (± 30.360)	-17.70 (± 23.161)	-21.84 (± 27.812)
% Overall Work Impairment : Baseline tp Week 52	-17.29 (± 33.754)	-10.17 (± 27.793)	-18.62 (± 28.397)	-16.20 (± 32.59)
% Overall Work Impairment : Baseline to Week 12	-7.78 (± 24.016)	-11.74 (± 22.736)	-21.17 (± 25.287)	-21.92 (± 26.378)
% Overall Work Impairment : Baseline to Week 24	-7.18 (± 26.552)	-13.78 (± 19.690)	-22.42 (± 25.547)	-22.32 (± 26.481)
% Overall Work Impairment : Baseline to Week 36	-10.65 (± 23.655)	-15.24 (± 20.150)	-23.43 (± 25.748)	-25.34 (± 26.927)
% Overall Work Impairment : Baseline to Week 52	-10.88 (± 28.001)	-14.88 (± 20.044)	-22.95 (± 24.656)	-23.93 (± 27.743)

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Plasma Concentrations of Ruxolitinib During the VC Period

End point title	Trough Plasma Concentrations of Ruxolitinib During the VC Period[11]

End point description:

End point type	Secondary

End point timeframe:

Weeks 2, 4 and 8

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No C trough values calculated for the Vehicle group

End point values	VC Period: Ruxolitinib 0.75% Cream BID	VC Period: Ruxolitinib 1.5% Cream BID		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	236	238		
Units: nanomole per litre (nM)				
arithmetic mean (standard deviation)				
Week 2	25.2 (± 37.4)	38.5 (± 64.5)		
Week 4	22.6 (± 35.2)	41.8 (± 83.6)		
Week 8	22.4 (± 36.1)	36.1 (± 66.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Plasma Concentrations of Ruxolitinib During the LTS Period

End point title	Trough Plasma Concentrations of Ruxolitinib During the LTS Period

End point description:

End point type	Secondary

End point timeframe:

Weeks 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52

End point values	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID	LTS Period: Ruxolitinib 0.75% Cream BID	LTS Period: Ruxolitinib 1.5% Cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	51	198	215
Units: nM				
arithmetic mean (standard deviation)				
Week 12	13.8 (± 22.7)	23.9 (± 55.2)	14.3 (± 26.9)	22.6 (± 46.6)
Week 16	12.3 (± 22.8)	16.1 (± 27.7)	15.1 (± 28.3)	23.9 (± 45.9)
Week 20	18.8 (± 41.0)	25.3 (± 43.9)	13.6 (± 20.5)	26.8 (± 55.9)
Week 24	11.7 (± 26.0)	27.6 (± 62.4)	18.5 (± 49.8)	25.7 (± 56.9)
Week 28	20.4 (± 39.9)	17.6 (± 32.2)	16.1 (± 36.1)	20.8 (± 39.8)
Week 32	14.6 (± 30.6)	26.4 (± 51.3)	14.0 (± 23.2)	25.9 (± 67.8)
Week 36	11.4 (± 23.7)	29.9 (± 52.8)	15.0 (± 28.4)	22.0 (± 40.1)
Week 40	12.6 (± 36.7)	32.8 (± 59.4)	20.0 (± 51.1)	26.3 (± 59.4)
Week 44	15.9 (± 31.9)	23.0 (± 33.7)	14.8 (± 28.8)	24.1 (± 40.9)
Week 48	16.8 (± 38.6)	35.7 (± 64.5)	23.4 (± 58.1)	26.3 (± 54.3)
Week 52	12.9 (± 21.8)	35.7 (± 65.2)	17.7 (± 33.9)	23.3 (± 48.1)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
60 weeks	
Adverse event reporting additional description:	
AE additional description	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21

Reporting groups	
Reporting group title	VC and LTS Period: Vehicle Cream BID
Reporting group description:	
VC and LTS Period: Vehicle Cream BID Participants received vehicle cream, applied topically to the affected areas as a thin film BID from Day 1 to Week 8 during the VC Period. Participants from Vehicle cream arm were crossed over to 0.75 or 1.5mg rux BID	
Reporting group title	VC and LTS Period: Ruxolitinib 1.5% Cream BID
Reporting group description:	
Participants received ruxolitinib 1.5% cream, applied topically to the affected areas as a thin film BID from Day 1 to Week 8 during the VC Period. Participants from Vehicle cream arm were crossed over to 1.5 rux BID.	
Reporting group title	VC and LTS Period: Ruxolitinib 0.75% Cream BID
Reporting group description:	
Participants received ruxolitinib 0.75% cream, applied topically to the affected areas as a thin film BID from Day 1 to Week 8 during the VC Period. Participants from Vehicle cream arm were crossed over to 0.75 rux BID.	

Serious adverse events	VC and LTS Period: Vehicle Cream BID	VC and LTS Period: Ruxolitinib 1.5% Cream BID	VC and LTS Period: Ruxolitinib 0.75% Cream BID
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 124 (0.00%)	4 / 298 (1.34%)	8 / 301 (2.66%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 124 (0.00%)	0 / 298 (0.00%)	1 / 301 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			

subjects affected / exposed	0 / 124 (0.00%)	0 / 298 (0.00%)	1 / 301 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 124 (0.00%)	1 / 298 (0.34%)	0 / 301 (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
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 124 (0.00%)	1 / 298 (0.34%)	0 / 301 (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
Myocardial infarction			
subjects affected / exposed	0 / 124 (0.00%)	0 / 298 (0.00%)	1 / 301 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 124 (0.00%)	1 / 298 (0.34%)	1 / 301 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst ruptured			
subjects affected / exposed	0 / 124 (0.00%)	0 / 298 (0.00%)	1 / 301 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	0 / 124 (0.00%)	0 / 298 (0.00%)	1 / 301 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			

subjects affected / exposed	0 / 124 (0.00%)	1 / 298 (0.34%)	0 / 301 (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
Pulmonary embolism			
subjects affected / exposed	0 / 124 (0.00%)	1 / 298 (0.34%)	0 / 301 (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
Infections and infestations			
Chronic tonsillitis			
subjects affected / exposed	0 / 124 (0.00%)	1 / 298 (0.34%)	0 / 301 (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
Pneumonia			
subjects affected / exposed	0 / 124 (0.00%)	0 / 298 (0.00%)	1 / 301 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 298 (0.00%)	1 / 301 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 298 (0.00%)	1 / 301 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			
subjects affected / exposed	0 / 124 (0.00%)	0 / 298 (0.00%)	1 / 301 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	VC and LTS Period: Vehicle Cream BID	VC and LTS Period: Ruxolitinib 1.5% Cream BID	VC and LTS Period: Ruxolitinib 0.75% Cream BID
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 124 (7.26%)	51 / 298 (17.11%)	49 / 301 (16.28%)
General disorders and administration site conditions			
Application site pain			
subjects affected / exposed	8 / 124 (6.45%)	2 / 298 (0.67%)	2 / 301 (0.66%)
occurrences (all)	8	3	2
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	1 / 124 (0.81%)	23 / 298 (7.72%)	23 / 301 (7.64%)
occurrences (all)	1	28	26
Nasopharyngitis			
subjects affected / exposed	0 / 124 (0.00%)	27 / 298 (9.06%)	28 / 301 (9.30%)
occurrences (all)	0	39	43

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported