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	2018-003712-45
Trial protocol	DE HU FR PL IT
Global end of trial date	01 December 2020

Results information

Result version number	v1 (current)
This version publication date	03 December 2021
First version publication date	03 December 2021

Trial information

Trial identification

Sponsor protocol code	INCB 18424-303

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Incyte
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	01 December 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 December 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 and safety of twice daily 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	Canada: 49
Country: Number of subjects enrolled	France: 9
Country: Number of subjects enrolled	Germany: 6
Country: Number of subjects enrolled	Hungary: 17
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Poland: 153
Country: Number of subjects enrolled	United States: 391
Worldwide total number of subjects	631
EEA total number of subjects	191

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)	123
Adults (18-64 years)	450
From 65 to 84 years	57
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

A total of 631 participants took part in the study at 78 sites, 48 in North America and 30 in Europe from December 20, 2018 to December 01, 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	Subject, Investigator, Carer, Data analyst

Arms

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

Arm description:

Participants received vehicle cream, applied topically to the affected areas as a thin film twice daily (BID) from Day 1 to Week 8 during the VC Period.

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 a Day

Arm title	VC Period: Ruxolitinib 0.75% Cream BID

Arm 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.

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 a Day

Arm title	VC Period: Ruxolitinib 1.5% Cream BID

Arm 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.

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 a Day

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	126	252	253
Completed	95	222	225
Not completed	31	30	28
Physician decision	1	1	-
Consent withdrawn by subject	17	11	19
Adverse event, non-fatal	4	2	1
Reason Not Specified	2	1	-
Pregnancy	1	-	-
Lost to follow-up	5	12	8
Lack of efficacy	1	-	-
Protocol deviation	-	3	-

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, Assessor

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 BID during the VC Period, were randomized to apply ruxolitinib 0.75% cream, topically to the affected areas as a thin film BID from Week 8 to 52 during the LTS Period.

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 a day

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

Arm description:

Participants who applied vehicle cream BID during the VC Period, were randomized to apply ruxolitinib 1.5% cream, topically to the affected areas as a thin film BID from Week 8 to 52 during the LTS Period.

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 a day

Arm title	LTS Period: Ruxolitinib 0.75% Cream

Arm description:

Participants who applied ruxolitinib 0.75% cream during VC Period, continued applying ruxolitinib 0.75% cream topically to the affected areas as a thin film BID from Week 8 to 52 during the LTS Period.

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 a day

Arm title	LTS Period: Ruxolitinib 1.5% Cream

Arm description:

Participants who applied ruxolitinib 1.5% cream during VC Period, continued applying ruxolitinib 1.5% cream topically to the affected areas as a thin film BID from Week 8 to 52 during the LTS Period.

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 a day

Number of subjects in period 2	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
Started	48	47	222
Completed	37	38	176
Not completed	11	9	46
Consent withdrawn by subject	7	3	17
Physician decision	-	1	3
Adverse event, non-fatal	-	-	6
Reason Not Specified	-	-	4
Lost to follow-up	3	5	13
Lack of efficacy	1	-	2
Protocol deviation	-	-	1

Number of subjects in period 2	LTS Period: Ruxolitinib 1.5% Cream
Started	225
Completed	174
Not completed	51
Consent withdrawn by subject	21
Physician decision	-
Adverse event, non-fatal	1
Reason Not Specified	3
Lost to follow-up	24
Lack of efficacy	2
Protocol deviation	-

Baseline characteristics

Reporting groups	
Reporting group title	VC Period: Vehicle Cream BID
Reporting group description:	
Participants received vehicle cream, applied topically to the affected areas as a thin film twice daily (BID) from Day 1 to Week 8 during the VC Period.	
Reporting group title	VC 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.	
Reporting group title	VC 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.	

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	126	252	253
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)	23	53	47
Adults (18-64 years)	92	171	187
From 65-84 years	11	27	19
85 years and over	0	1	0
Age Continuous Units: years			
arithmetic mean	35.2	36.8	33.7
standard deviation	± 18.11	± 19.06	± 17.15
Sex: Female, Male Units: participants			
Female	79	154	158
Male	47	98	95
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	21	30	37
Not Hispanic or Latino	104	218	212
Unknown or Not Reported	1	4	4
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	2	0
Asian	8	10	14
Native Hawaiian or Other Pacific Islander	0	3	0

Black or African American	29	55	56
White	85	173	177
More than one race	0	0	0
Unknown or Not Reported	4	9	6
Body Mass Index (BMI)			
Units: Kilograms per square metre (kg/m^2)			
arithmetic mean	26.92	27.33	27.47
standard deviation	± 6.245	± 6.745	± 8.077

Reporting group values	Total		
Number of subjects	631		
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)	123		
Adults (18-64 years)	450		
From 65-84 years	57		
85 years and over	1		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Units: participants			
Female	391		
Male	240		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	88		
Not Hispanic or Latino	534		
Unknown or Not Reported	9		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	2		
Asian	32		
Native Hawaiian or Other Pacific Islander	3		
Black or African American	140		
White	435		
More than one race	0		
Unknown or Not Reported	19		
Body Mass Index (BMI)			
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:	
Participants received vehicle cream, applied topically to the affected areas as a thin film twice daily (BID) from Day 1 to Week 8 during the VC Period.	
Reporting group title	VC 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.	
Reporting group title	VC 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.	
Reporting group title	LTS Period: Vehicle Cream to Ruxolitinib 0.75% Cream BID
Reporting group description:	
Participants who applied vehicle cream BID during the VC Period, were randomized to apply ruxolitinib 0.75% cream, topically to the affected areas as a thin film BID from Week 8 to 52 during the LTS Period.	
Reporting group title	LTS Period: Vehicle Cream to Ruxolitinib 1.5% Cream BID
Reporting group description:	
Participants who applied vehicle cream BID during the VC Period, were randomized to apply ruxolitinib 1.5% cream, topically to the affected areas as a thin film BID from Week 8 to 52 during the LTS Period.	
Reporting group title	LTS Period: Ruxolitinib 0.75% Cream
Reporting group description:	
Participants who applied ruxolitinib 0.75% cream during VC Period, continued applying ruxolitinib 0.75% cream topically to the affected areas as a thin film BID from Week 8 to 52 during the LTS Period.	
Reporting group title	LTS Period: Ruxolitinib 1.5% Cream
Reporting group description:	
Participants who applied ruxolitinib 1.5% cream during VC Period, continued applying ruxolitinib 1.5% cream topically to the affected areas as a thin film BID from Week 8 to 52 during the LTS Period.	

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	126	252	253	
Units: percentage of participants				
number (confidence interval 95%)	15.1 (9.3 to 22.5)	50.0 (43.7 to 56.3)	53.8 (47.4 to 60.0)	

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [1]
Method	Conditional Exact test
Parameter estimate	Odds ratio (OR)
Point estimate	7.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.178
upper limit	14.04

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 0.75% Cream BID
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [2]
Method	Conditional Exact test
Parameter estimate	Odds ratio (OR)
Point estimate	6.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.556
upper limit	11.923

Notes:

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

Secondary: VC Period: Percentage of Participants Who Achieved Eczema Area and Severity Index 75 (EASI75)

End point title	VC Period: Percentage of Participants Who Achieved Eczema Area and Severity Index 75 (EASI75)

End point description:

EASI scoring system examines 4 areas of the body 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) for an average degree of severity of each sign in each region. The severity strata for the EASI 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	126	252	253	
Units: percentage of participants				
number (confidence interval 95%)	24.6 (17.4 to 33.1)	56.0 (49.6 to 62.2)	62.1 (55.8 to 68.1)	

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	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [3]
Method	Conditional Exact test
Parameter estimate	Odds ratio (OR)
Point estimate	4.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.441
upper limit	6.808

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 1.5% Cream BID

Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [4]
Method	Conditional Exact test
Parameter estimate	Odds ratio (OR)
Point estimate	5.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.145
upper limit	8.831

Notes:

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

Secondary: VC Period: Percentage of Participants with a ≥ 4-Point Improvement in Itch Numerical Rating Scale (NRS) Score

End point title	VC Period: Percentage of Participants with a ≥ 4-Point Improvement in Itch Numerical Rating Scale (NRS) Score

End point description:

The Itch NRS is a daily participant-reported measure (24-hour recall), using a diary, of the worst level of itch intensity. Participants were asked to rate the itching severity because of their AD in the daily diary by selecting a number from 0 (no itch) to 10 (worst imaginable itch) that best described 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	78	156	161	
Units: percentage of participants				
number (not applicable)	15.4	40.4	52.2	

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	239
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [5]
Method	Conditional Exact test
Parameter estimate	Odds ratio (OR)
Point estimate	6.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.931
upper limit	13.22

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	234
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002 [6]
Method	Conditional Exact test
Parameter estimate	Odds ratio (OR)
Point estimate	3.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.773
upper limit	8.083

Notes:

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

Secondary: VC Period: Percentage 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

End point title	VC Period: Percentage 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

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. It is a 5-point scale with a range in score from 8 to 40, with higher scores indicating greater severity of sleep disturbance. Each item asks the participant to rate the severity of the participant's 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	116	233	238	
Units: percentage of participants				
number (not applicable)	9.5	21.0	22.3	

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	354
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0039 [7]
Method	Conditional Exact test
Parameter estimate	Odds ratio (OR)
Point estimate	2.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.334
upper limit	6.083

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 0.75% Cream BID
Number of subjects included in analysis	349
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0081 [8]
Method	Conditional Exact test
Parameter estimate	Odds ratio (OR)
Point estimate	2.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.242
upper limit	5.723

Notes:

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

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

End point title	VC Period: Percentage of Participants with a Clinically Meaningful (≥ 6-Point) Improvement in the PROMIS Short Form – Sleep-Related Impairment (8a – 24-Hour Recall)

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 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. Each item asks the participant to rate the severity of the participant's sleep 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	114	233	245	
Units: percentage of participants				
number (not applicable)	13.2	20.2	21.6	

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	347
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1421 [9]
Method	Conditional Exact test
Parameter estimate	Odds ratio (OR)
Point estimate	1.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.862
upper limit	3.391

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	359
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0746 [10]
Method	Conditional Exact test
Parameter estimate	Odds ratio (OR)
Point estimate	1.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.949
upper limit	3.665

Notes:

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

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

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

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 first dose 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	126	252	253	
Units: percentage of participants				
number (not applicable)				
TEAE	34.9	29.0	29.2	
Treatment Emergent SAE	1.6	0.4	0.8	

Statistical analyses

No statistical analyses for this end point

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

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

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	LTS Period: Ruxolitinib 1.5% Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	222	225
Units: percentage of participants				
number (not applicable)				
TEAE	47.9	48.9	54.5	53.3
Treatment Emergent SAE	6.3	2.1	2.3	1.3

Statistical analyses

No statistical analyses for this end point

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

End point title	VC Period: 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 0 (clear skin) to 4 (severe disease) scale. 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	126	252	253	
Units: percentage of participants				
number (not applicable)				
Week 2	3.2	22.2	27.3	
Week 4	6.3	42.5	46.6	

Statistical analyses

No statistical analyses for this end point

Secondary: VC Period: Percentage of Participants Achieving IGA Scores of 0 or 1

End point title	VC Period: Percentage of Participants Achieving IGA Scores of 0 or 1

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. IGA score signifies 0 (clear skin) and 1 (almost clear skin).

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	126	252	253	
Units: percentage of participants				
number (not applicable)				
Week 2	6.3	32.5	34.8	
Week 4	15.1	53.2	54.9	
Week 8	23.8	58.7	62.8	

Statistical analyses

No statistical analyses for this end point

Secondary: LTS Period: Percentage of Participants Achieving IGA Scores of 0 or 1

End point title	LTS Period: Percentage of Participants Achieving IGA Scores of 0 or 1

End point description:

The IGA is an overall eczema severity rating on a 0 (clear skin) to 4 (severe disease) scale. 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	LTS Period: Ruxolitinib 1.5% Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	222	225
Units: percentage of participants				
number (not applicable)				
Week 8	18.8	38.3	65.3	68.4
Week 12	55.6	65.2	62.7	66.5
Week 16	60.5	62.2	66.5	68.9
Week 20	63.6	67.4	62.4	73.5
Week 24	71.4	78.6	67.0	76.7
Week 28	64.9	74.4	67.3	77.3
Week 32	77.1	81.4	71.5	75.9
Week 36	73.5	82.1	74.5	71.7
Week 40	81.3	79.5	73.5	75.5
Week 44	84.8	86.5	74.3	76.2
Week 48	72.2	76.3	74.3	73.8
Week 52	76.3	73.7	76.9	75.4

Statistical analyses

No statistical analyses for this end point

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

End point title	VC Period: 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), using a diary, of the worst level of itch intensity. 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	78	156	161	
Units: percentage of participants				
number (not applicable)				
Week 2	5.1	26.3	33.5	
Week 4	11.5	38.5	51.6	

Statistical analyses

No statistical analyses for this end point

Secondary: VC period: Percentage of Participants Achieving EASI50

End point title	VC period: Percentage of Participants Achieving EASI50

End point description:

EASI scoring system examines 4 areas of the body 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) for an average degree of severity of each sign in each region. The severity strata for the EASI 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:

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	126	252	253	
Units: percentage of participants				
number (not applicable)				
Week 2	19.8	53.2	62.5	
Week 4	27.8	68.7	75.5	
Week 8	43.7	69.4	77.9	

Statistical analyses

No statistical analyses for this end point

Secondary: VC Period: Percentage of Participants Achieving EASI75

End point title	VC Period: Percentage of Participants Achieving EASI75

End point description:

EASI scoring system examines 4 areas of the body 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) for an average degree of severity of each sign in each region. The severity strata for the EASI 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:

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	126	252	253	
Units: percentage of participants				
number (not applicable)				
Week 2	5.6	30.2	36.0	
Week 4	14.3	51.6	58.5	

Statistical analyses

No statistical analyses for this end point

Secondary: VC Period: Percentage of Participants Achieving EASI90

End point title	VC Period: Percentage of Participants Achieving EASI90

End point description:

EASI scoring system examines 4 areas of the body 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) for an average degree of severity of each sign in each region. The severity strata for the EASI 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:

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	126	252	253	
Units: percentage of participants				
number (not applicable)				
Week 2	2.4	12.7	19.8	
Week 4	4.0	30.6	36.4	
Week 8	9.5	38.1	44.3	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

EASI scoring system examines 4 areas of the body 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) for an average degree of severity of each sign in each region. The severity strata for the EASI 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	126	252	253	
Units: percent change				
least squares mean (standard error)				
Percent Change From Baseline at Week 2	-16.34 (± 3.42)	-51.82 (± 2.36)	-56.62 (± 2.35)	
Percent Change From Baseline at Week 4	-23.03 (± 3.90)	-68.04 (± 2.66)	-71.08 (± 2.64)	
Percent Change From Baseline at Week 8	-37.88 (± 3.72)	-71.01 (± 2.52)	-77.40 (± 2.49)	

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-35.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.64
upper limit	-27.32
Variability estimate	Standard error of the mean
Dispersion value	4.16

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Method of Mean Difference]
Point estimate	-40.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-48.44
upper limit	-32.13
Variability estimate	Standard error of the mean
Dispersion value	4.15

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-45.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-54.28
upper limit	-35.74
Variability estimate	Standard error of the mean
Dispersion value	4.72

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-48.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-57.3
upper limit	-38.79
Variability estimate	Standard error of the mean
Dispersion value	4.71

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [11]
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-33.13

Confidence interval	
level	95 %
sides	2-sided
lower limit	-41.95
upper limit	-24.3
Variability estimate	Standard error of the mean
Dispersion value	4.49

Notes:

[11] - The MMRM included the fixed effect of treatment, stratification factor, the visit, and treatment by visit interaction.

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-39.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-48.32
upper limit	-30.72
Variability estimate	Standard error of the mean
Dispersion value	4.48

Secondary: VC Period: Percent Change From Baseline In SCORing Atopic Dermatitis (SCORAD) Score

End point title	VC Period: Percent Change From Baseline In SCORing Atopic Dermatitis (SCORAD) Score

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	126	252	253	
Units: percent change				
arithmetic mean (standard deviation)				
Percent Change From Baseline at Week 2	-16.67 (± 34.152)	-43.96 (± 28.548)	-49.32 (± 31.878)	
Percent Change From Baseline at Week 4	-27.68 (± 34.518)	-57.80 (± 28.635)	-61.33 (± 30.113)	
Percent Change From Baseline at Week 8	-37.00 (± 36.392)	-62.14 (± 31.108)	-67.24 (± 28.711)	

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 1.5% Cream BID
Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-30.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.68
upper limit	-23.06
Variability estimate	Standard error of the mean
Dispersion value	3.72

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-25.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.62
upper limit	-17.95
Variability estimate	Standard error of the mean
Dispersion value	3.74

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

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

End point description:

The Itch NRS is a daily participant-reported measure (24-hour recall), using a diary, of the worst level of itch intensity. 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	126	252	253	
Units: score on a scale				
least squares mean (standard error)				
Change From Baseline at Week 2	-0.89 (± 0.20)	-2.28 (± 0.14)	-2.53 (± 0.13)	
Change From Baseline at Week 4	-1.08 (± 0.23)	-2.79 (± 0.16)	-3.16 (± 0.15)	
Change From Baseline at Week 8	-1.54 (± 0.25)	-3.14 (± 0.17)	-3.53 (± 0.16)	

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.39

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.87
upper limit	-0.91
Variability estimate	Standard error of the mean
Dispersion value	0.24

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.11
upper limit	-1.16
Variability estimate	Standard error of the mean
Dispersion value	0.24

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	-1.01
Variability estimate	Standard error of the mean
Dispersion value	0.3

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	378
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	-2.25
upper limit	-1.15
Variability estimate	Standard error of the mean
Dispersion value	0.28

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-2.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.63
upper limit	-1.53
Variability estimate	Standard error of the mean
Dispersion value	0.28

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.58
upper limit	-1.4
Variability estimate	Standard error of the mean
Dispersion value	0.3

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

End point title	VC Period: Time to Achieve Itch NRS Score Improvement of at Least 2, 3, or 4 Points

End point description:

The Itch NRS is a daily participant-reported measure (24-hour recall), using a diary, of the worst level of itch intensity. Participants were 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	126	252	253	
Units: days				
median (confidence interval 95%)				
≥ 2-Point Improvement in Itch NRS Score	15.0 (10.0 to 22.0)	4.0 (3.0 to 5.0)	3.0 (3.0 to 4.0)	
≥ 3-Point Improvement in Itch NRS Score	27.0 (13.0 to 69.0)	8.0 (7.0 to 11.0)	6.0 (5.0 to 9.0)	
≥ 4-Point Improvement in Itch NRS Score	99999 (9.9999 to 999999)	14.0 (9.0 to 19.0)	13.0 (9.0 to 15.0)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The Skin Pain NRS is a daily patient-reported measure (24-hour recall), using a ediary, of the worst level of pain intensity from 0 (no pain) to 10 (worst imaginable pain). Participants will be 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	126	252	253	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2	-0.70 (± 1.746)	-1.90 (± 1.950)	-2.07 (± 2.164)	
Change From Baseline at Week 4	-0.84 (± 2.307)	-2.36 (± 2.217)	-2.72 (± 2.513)	
Change From Baseline at Week 8	-1.16 (± 2.610)	-2.55 (± 2.360)	-2.84 (± 2.743)	

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 1.5% Cream BID
Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.11
upper limit	-1.13
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 0.75% Cream BID
Number of subjects included in analysis	378
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	-1.74
upper limit	-0.74
Variability estimate	Standard error of the mean
Dispersion value	0.25

Secondary: VC Period: Percentage of Participants With a Clinically Meaningful (≥ 6-Point) Improvement in the PROMIS Short Form - Sleep Disturbance (8b) 24-Hour Recall Score

End point title	VC Period: Percentage of Participants With a Clinically Meaningful (≥ 6-Point) Improvement in the PROMIS Short Form - Sleep Disturbance (8b) 24-Hour Recall Score
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	116	233	238	
Units: percentage of participants				
number (not applicable)				
Week 2	5.2	13.7	14.7	
Week 4	6.9	19.3	21.0	

Week 8	9.5	21.0	22.3	

Statistical analyses

No statistical analyses for this end point

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

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

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	114	233	245	
Units: percentage of participants				
number (not applicable)				
Week 2	8.8	16.3	13.5	
Week 4	13.2	20.6	19.2	
Week 8	13.2	20.2	21.6	

Statistical analyses

No statistical analyses for this end point

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

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

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	126	252	253	
Units: score on a scale				
least squares mean (standard error)				
Change From Baseline at Week 2	-0.18 (± 0.45)	-1.72 (± 0.31)	-2.49 (± 0.30)	
Change From Baseline at Week 4	-0.25 (± 0.50)	-2.58 (± 0.34)	-3.10 (± 0.33)	
Change From Baseline at Week 8	-0.43 (± 0.59)	-2.97 (± 0.39)	-3.62 (± 0.39)	

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0049
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	-2.6
upper limit	-0.47
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 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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-2.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.37
upper limit	-1.25
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 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	378
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-2.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.52
upper limit	-1.15
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 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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-2.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.03
upper limit	-1.67
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 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	378
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0004
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-2.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.93
upper limit	-1.14
Variability estimate	Standard error of the mean
Dispersion value	0.71

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.18

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.57
upper limit	-1.79
Variability estimate	Standard error of the mean
Dispersion value	0.71

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

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

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	126	252	253	
Units: score on a scale				
least squares mean (standard error)				
Change From Baseline at Week 2	-0.58 (± 0.49)	-1.76 (± 0.33)	-2.25 (± 0.33)	
Change From Baseline at Week 4	-1.06 (± 0.55)	-2.71 (± 0.37)	-2.97 (± 0.36)	
Change From Baseline at Week 8	-1.22 (± 0.62)	-3.34 (± 0.41)	-3.52 (± 0.40)	

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0487
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	-2.35
upper limit	-0.01
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 2	
Comparison groups	VC Period: Vehicle Cream BID v VC Period: Ruxolitinib 1.5% Cream BID
Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0049
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.84
upper limit	-0.51
Variability estimate	Standard error of the mean
Dispersion value	0.59

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0128
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.94
upper limit	-0.35
Variability estimate	Standard error of the mean
Dispersion value	0.66

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0037
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	-0.62
Variability estimate	Standard error of the mean
Dispersion value	0.66

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0048
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-2.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.58
upper limit	-0.65
Variability estimate	Standard error of the mean
Dispersion value	0.75

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.002
Method	Mixed-Model with Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.75
upper limit	-0.84
Variability estimate	Standard error of the mean
Dispersion value	0.74

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

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

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	LTS Period: Ruxolitinib 1.5% Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	222	225
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 12	-1.51 (± 4.739)	-2.22 (± 7.305)	-0.39 (± 3.984)	-0.39 (± 3.907)
Change From Baseline at Week 24	-0.54 (± 5.211)	-2.66 (± 7.268)	0.11 (± 4.929)	0.02 (± 5.584)
Change From Baseline at Week 52	-0.97 (± 5.085)	-2.81 (± 7.005)	-0.37 (± 5.775)	-0.54 (± 5.511)

Statistical analyses

No statistical analyses for this end point

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

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

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	LTS Period: Ruxolitinib 1.5% Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	222	225
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 12	-1.93 (± 5.284)	-2.67 (± 7.160)	-0.67 (± 4.575)	-0.66 (± 3.865)

Change From Baseline at Week 24	-1.22 (± 5.681)	-3.15 (± 8.242)	0.02 (± 5.536)	0.51 (± 5.563)
Change From Baseline at Week 52	-1.95 (± 4.876)	-3.31 (± 7.082)	-0.27 (± 6.506)	-0.07 (± 5.918)

Statistical analyses

No statistical analyses for this end point

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

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

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. Used 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	126	252	253	
Units: % BSA				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2	-0.43 (± 5.559)	-3.69 (± 4.230)	-3.76 (± 4.238)	
Change From Baseline at Week 4	-1.56 (± 4.088)	-5.29 (± 4.969)	-5.25 (± 5.190)	
Change From Baseline at Week 8	-2.51 (± 4.722)	-6.30 (± 5.378)	-6.54 (± 4.967)	

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 1.5% Cream BID

Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.67
upper limit	-2.79
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 0.75% Cream BID
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.07
upper limit	-2.18
Variability estimate	Standard error of the mean
Dispersion value	0.48

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

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

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. Used 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	LTS Period: Ruxolitinib 1.5% Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	222	225
Units: % BSA				
arithmetic mean (standard deviation)				
Change From Baseline at Week 12	-4.23 (± 4.849)	-2.84 (± 4.907)	-6.84 (± 4.852)	-6.96 (± 4.989)
Change From Baseline at Week 16	-4.96 (± 5.194)	-2.98 (± 5.429)	-7.36 (± 4.875)	-7.26 (± 5.080)
Change From Baseline at Week 20	-4.78 (± 5.095)	-3.75 (± 5.321)	-7.69 (± 4.901)	-7.49 (± 5.012)
Change From Baseline at Week 24	-5.32 (± 4.964)	-3.85 (± 5.223)	-7.64 (± 4.998)	-7.64 (± 4.737)
Change From Baseline at Week 28	-4.56 (± 5.486)	-4.43 (± 4.995)	-7.66 (± 5.029)	-7.62 (± 4.913)
Change From Baseline at Week 32	-5.17 (± 4.472)	-4.53 (± 5.399)	-7.80 (± 5.011)	-7.61 (± 5.261)
Change From Baseline at Week 36	-5.21 (± 4.972)	-4.39 (± 5.509)	-8.18 (± 5.111)	-7.97 (± 5.010)
Change From Baseline at Week 40	-4.67 (± 5.519)	-4.75 (± 5.337)	-8.07 (± 4.899)	-8.11 (± 4.997)
Change From Baseline at Week 44	-5.28 (± 5.173)	-4.56 (± 5.609)	-8.14 (± 4.789)	-8.02 (± 4.939)
Change From Baseline at Week 48	-5.65 (± 5.128)	-4.58 (± 5.696)	-8.39 (± 5.023)	-7.96 (± 4.993)
Change From Baseline at Week 52	-5.72 (± 5.481)	-4.93 (± 5.771)	-8.58 (± 5.013)	-8.14 (± 4.906)

Statistical analyses

No statistical analyses for this end point

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

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

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	126	252	253	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2	-2.25 (± 5.779)	-9.47 (± 7.212)	-10.60 (± 6.670)	
Change From Baseline at Week 4	-3.38 (± 6.685)	-10.12 (± 7.380)	-11.53 (± 6.891)	
Change From Baseline at Week 8	-4.30 (± 7.044)	-10.60 (± 7.262)	-11.82 (± 6.931)	

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-5.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.43
upper limit	-3.8
Variability estimate	Standard error of the mean
Dispersion value	0.67

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-6.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.62
upper limit	-5
Variability estimate	Standard error of the mean
Dispersion value	0.67

Secondary: LTS Period: Change From Baseline in POEM Score

End point title	LTS Period: Change From Baseline in POEM Score

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	LTS Period: Ruxolitinib 1.5% Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	46	206	206
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 12	-5.95 (± 6.607)	-6.89 (± 9.730)	-10.74 (± 6.653)	-11.38 (± 6.710)
Change From Baseline at Week 24	-4.46 (± 6.185)	-7.26 (± 9.189)	-10.46 (± 6.655)	-11.44 (± 6.689)
Change From Baseline at Week 52	-4.61 (± 6.868)	-7.00 (± 8.752)	-10.51 (± 7.396)	-10.61 (± 7.057)

Statistical analyses

No statistical analyses for this end point

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

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

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	107	215	223	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2	-1.54 (± 4.618)	-6.18 (± 5.740)	-6.90 (± 5.980)	
Change From Baseline at Week 4	-2.50 (± 6.101)	-6.88 (± 5.867)	-7.15 (± 6.565)	
Change From Baseline at Week 8	-2.83 (± 6.722)	-7.28 (± 5.907)	-7.72 (± 6.152)	

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	322
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.85
upper limit	-2.68
Variability estimate	Standard error of the mean
Dispersion value	0.55

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	330
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	-5.56
upper limit	-3.42
Variability estimate	Standard error of the mean
Dispersion value	0.55

Secondary: LTS Period: Change From Baseline in DLQI Score

End point title	LTS Period: Change From Baseline in DLQI Score

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	LTS Period: Ruxolitinib 1.5% Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	38	189	200
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 12	-3.65 (± 5.602)	-4.53 (± 6.246)	-7.67 (± 5.855)	-7.79 (± 6.240)
Change From Baseline at Week 24	-3.21 (± 4.814)	-5.32 (± 6.304)	-7.87 (± 6.080)	-7.75 (± 6.277)
Change From Baseline at Week 52	-3.35 (± 5.438)	-4.81 (± 6.720)	-7.95 (± 6.589)	-7.70 (± 6.443)

Statistical analyses

No statistical analyses for this end point

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

End point title	VC Period: Change From Baseline in Children Dermatology Life Quality Index (CDLQI) Score

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	19	37	30	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2	-1.06 (± 3.733)	-5.06 (± 6.937)	-6.76 (± 6.306)	
Change From Baseline at Week 4	-2.47 (± 6.530)	-4.35 (± 8.683)	-6.90 (± 5.101)	
Change From Baseline at Week 8	-2.31 (± 5.618)	-5.88 (± 7.524)	-7.61 (± 6.142)	

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	56
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0018
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.29
upper limit	-1.26
Variability estimate	Standard error of the mean
Dispersion value	1.01

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	49
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0378
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.43
upper limit	-0.13
Variability estimate	Standard error of the mean
Dispersion value	1.08

Secondary: LTS Period: Change From Baseline in CDLQI Score

End point title	LTS Period: Change From Baseline in CDLQI Score

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	LTS Period: Ruxolitinib 1.5% Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	33	25
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 12	-4.00 (± 5.477)	-1.13 (± 8.907)	-5.83 (± 7.661)	-8.86 (± 5.532)
Change From Baseline at Week 24	-2.71 (± 5.155)	-2.00 (± 3.780)	-6.72 (± 7.640)	-9.42 (± 7.214)
Change From Baseline at Week 52	-4.33 (± 8.359)	-0.43 (± 4.928)	-6.70 (± 7.766)	-9.71 (± 6.262)

Statistical analyses

No statistical analyses for this end point

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

End point title	VC Period: 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	126	252	253	
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 2	3.53 (± 1.500)	2.06 (± 0.937)	1.94 (± 0.911)	
Week 4	3.30 (± 1.434)	1.78 (± 0.903)	1.68 (± 0.843)	
Week 8	3.08 (± 1.489)	1.76 (± 0.913)	1.61 (± 0.914)	

Statistical analyses

No statistical analyses for this end point

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

End point title	VC Period: Percentage 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	126	252	253	
Units: percentage of participants				
number (not applicable)				
Week 2 - Very Much Improved: 1	5.3	31.4	36.7	
Week 2 - Much Improved: 2	18.6	38.6	40.1	
Week 2 - Minimally Improved: 3	37.2	25.0	16.9	
Week 2 - No Change: 4	13.3	4.2	5.5	
Week 2 - Minimally Worse: 5	11.5	0.4	0.8	
Week 2 - Much Worse: 6	10.6	0.0	0.0	
Week 2 - Very Much Worse: 7	3.5	0.4	0.0	
Week 4 - Very Much Improved: 1	6.7	48.5	51.7	
Week 4 - Much Improved: 2	22.9	29.5	32.1	

Week 4 - Minimally Improved: 3	38.1	18.1	13.3	
Week 4 - No Change: 4	11.4	3.0	2.1	
Week 4 - Minimally Worse: 5	11.4	0.8	0.8	
Week 4 - Much Worse: 6	6.7	0.0	0.0	
Week 4 - Very Much Worse: 7	2.9	0.0	0.0	
Week 8 - Very Much Improved: 1	11.0	48.4	59.8	
Week 8 - Much Improved: 2	30.0	33.2	25.8	
Week 8 - Minimally Improved: 3	29.0	14.8	10.0	
Week 8 - No Change: 4	12.0	1.3	2.2	
Week 8 - Minimally Worse: 5	7.0	2.2	2.2	
Week 8 - Much Worse: 6	10.0	0.0	0.0	
Week 8 - Very Much Worse: 7	1.0	0.0	0.0	

Statistical analyses

No statistical analyses for this end point

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

End point title	VC Period: Percentage 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	126	252	253	
Units: percentage of participants				
number (confidence interval 95%)				
Week 2	23.9 (16.4 to 32.8)	69.9 (63.6 to 75.7)	76.8 (70.9 to 82.0)	
Week 4	29.5 (21.0 to 39.2)	78.1 (72.2 to 83.2)	83.8 (78.5 to 88.2)	
Week 8	41.0 (31.3 to 51.3)	81.6 (75.9 to 86.5)	85.6 (80.4 to 89.9)	

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 1.5% Cream BID
Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Conditional Exact test
Parameter estimate	Odds ratio (OR)
Point estimate	8.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.755
upper limit	15.083

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Conditional Exact test
Parameter estimate	Odds ratio (OR)
Point estimate	6.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.632
upper limit	11.018

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

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

End point description:

EQ-5D-5L questionnaire has 2 parts: 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

describes the participant's health. 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	126	252	253	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change From Baseline at Week 2	-0.94 (± 14.046)	6.93 (± 17.690)	8.21 (± 15.770)	
Change From Baseline at Week 4	1.76 (± 11.618)	8.73 (± 17.494)	7.10 (± 16.697)	
Change From Baseline at Week 8	1.74 (± 14.376)	9.12 (± 17.871)	7.98 (± 16.813)	

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 0.75% Cream BID
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0037
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.59
upper limit	8.15
Variability estimate	Standard error of the mean
Dispersion value	1.67

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0006
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	5.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.45
upper limit	8.96
Variability estimate	Standard error of the mean
Dispersion value	1.66

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

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

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	126	252	253	
Units: score on a scale				
arithmetic mean (standard deviation)				
Percent Work : Change From Baseline at Week 2	4.45 (± 19.542)	-3.89 (± 24.223)	1.19 (± 14.954)	
Percent Work : Change From Baseline at Week 4	14.09 (± 30.660)	1.22 (± 23.898)	3.43 (± 17.242)	
Percent Work : Change From Baseline at Week 8	5.07 (± 23.253)	-0.26 (± 23.891)	6.23 (± 22.211)	
Percent Impairment : From Baseline at Week 2	-7.36 (± 22.630)	-15.00 (± 22.494)	-16.75 (± 20.951)	

Percent Impairment : From Baseline at Week 4	-9.56 (± 25.580)	-16.86 (± 22.417)	-19.43 (± 20.933)	
Percent Impairment : From Baseline at Week 8	-13.54 (± 28.019)	-19.43 (± 24.878)	-21.61 (± 22.071)	
% Overall Impairment: From Baseline at Week 2	-5.27 (± 21.539)	-15.04 (± 27.812)	-15.49 (± 23.785)	
% Overall Impairment: From Baseline at Week 4	-2.35 (± 27.602)	-13.82 (± 26.207)	-15.82 (± 25.545)	
% Overall Impairment: From Baseline at Week 8	-9.01 (± 31.735)	-18.09 (± 27.718)	-15.54 (± 27.119)	
% Activity Impairment: From Baseline at Week 2	-6.32 (± 23.434)	-16.58 (± 24.696)	-21.56 (± 24.695)	
% Activity Impairment: From Baseline at Week 4	-10.09 (± 26.349)	-20.80 (± 24.107)	-23.53 (± 25.422)	
% Activity Impairment: From Baseline at Week 8	-11.70 (± 28.992)	-21.30 (± 24.653)	-24.06 (± 26.682)	

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1417
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.49
upper limit	1.65
Variability estimate	Standard error of the mean
Dispersion value	3.34

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6037
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.19
upper limit	4.77
Variability estimate	Standard error of the mean
Dispersion value	3.29

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0003
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.89
upper limit	-5.12
Variability estimate	Standard error of the mean
Dispersion value	2.99

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-12.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.98
upper limit	-6.47
Variability estimate	Standard error of the mean
Dispersion value	2.93

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-15.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.95
upper limit	-7.81
Variability estimate	Standard error of the mean
Dispersion value	3.85

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0011
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-12.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.85
upper limit	-5.01
Variability estimate	Standard error of the mean
Dispersion value	3.77

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	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.64
upper limit	-6.29
Variability estimate	Standard error of the mean
Dispersion value	2.13

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	379
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-12.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.6
upper limit	-8.29
Variability estimate	Standard error of the mean
Dispersion value	2.12

Secondary: LTS Period: Change From Baseline in WPAI-SHP v2.0	
End point title	LTS Period: Change From Baseline in WPAI-SHP v2.0

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	LTS Period: Ruxolitinib 1.5% Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	22	98	110
Units: score on a scale				
arithmetic mean (standard deviation)				
% Work Missed : Change From Baseline at Week 12	-4.78 (± 18.023)	-2.02 (± 4.902)	-0.26 (± 27.118)	7.72 (± 22.067)
% Work Missed : Change From Baseline at Week 24	-0.39 (± 21.466)	4.77 (± 16.899)	-1.00 (± 28.511)	4.96 (± 18.942)
% Work Missed : Change From Baseline at Week 36	-3.92 (± 23.687)	-3.12 (± 6.143)	-0.32 (± 27.115)	8.93 (± 21.916)
% Work Missed : Change From Baseline at Week 52	-8.11 (± 18.718)	3.23 (± 26.008)	1.81 (± 26.094)	2.38 (± 16.245)
% Impairment Change From Baseline in at Week 12	-11.50 (± 23.458)	-18.64 (± 28.668)	-20.21 (± 24.925)	-20.65 (± 21.844)
% Impairment Change From Baseline in at Week 24	-8.42 (± 16.754)	-16.67 (± 28.697)	-23.51 (± 25.067)	-23.66 (± 24.396)
% Impairment Change From Baseline in at Week 36	-3.13 (± 20.887)	-8.46 (± 33.378)	-23.15 (± 25.813)	-22.72 (± 23.185)
% Impairment Change From Baseline in at Week 52	-10.00 (± 25.166)	-20.00 (± 27.634)	-23.42 (± 26.597)	-22.77 (± 24.109)
% Overall Impairment: From Baseline at Week 12	-12.18 (± 24.763)	-19.64 (± 28.842)	-18.21 (± 28.345)	-14.99 (± 28.777)
% Overall Impairment: From Baseline at Week 24	-7.46 (± 16.254)	-12.96 (± 34.336)	-20.26 (± 31.191)	-18.60 (± 28.284)
% Overall Impairment: From Baseline at Week 36	-5.70 (± 23.040)	-10.43 (± 33.034)	-20.52 (± 31.307)	-14.86 (± 29.482)
% Overall Impairment: From Baseline at Week 52	-16.36 (± 29.721)	-16.67 (± 40.350)	-19.42 (± 29.878)	-20.50 (± 26.949)
% Activity Impairment: From Baseline at Week 12	-12.20 (± 21.273)	-8.48 (± 26.244)	-21.50 (± 26.470)	-25.19 (± 26.314)
% Activity Impairment: From Baseline at Week 24	-11.46 (± 16.517)	-7.14 (± 25.113)	-22.83 (± 27.440)	-27.47 (± 25.943)
% Activity Impairment: From Baseline at Week 36	-6.39 (± 18.997)	-1.25 (± 27.845)	-24.48 (± 26.203)	-26.84 (± 27.493)
% Activity Impairment: From Baseline at Week 52	-11.05 (± 24.910)	-13.42 (± 25.392)	-22.91 (± 27.669)	-26.92 (± 28.042)

Statistical analyses

No statistical analyses for this end point

Secondary: VC Period: Trough Plasma Concentrations of Ruxolitinib

End point title	VC Period: Trough Plasma Concentrations of Ruxolitinib[12]

End point description:

End point type	Secondary

End point timeframe:

Weeks 2, 4 and 8

Notes:

[12] - 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: Since VC group is a placebo no Trough plasma concentrations were measured.

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	241		
Units: nanomole per liter (nM)				
arithmetic mean (standard deviation)				
Week 2	26.8 (± 51.2)	33.4 (± 49.9)		
Week 4	25.1 (± 42.7)	34.7 (± 43.3)		
Week 8	24.0 (± 39.7)	33.3 (± 49.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: LTS Period: Trough Plasma Concentrations of Ruxolitinib

End point title	LTS Period: Trough Plasma Concentrations of Ruxolitinib

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	LTS Period: Ruxolitinib 1.5% Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	47	210	213
Units: nM				

arithmetic mean (standard deviation)				
Week 12	13.8 (± 21.3)	21.9 (± 34.4)	16.5 (± 28.1)	24.9 (± 45.4)
Week 16	11.9 (± 18.8)	18.1 (± 34.6)	19.7 (± 58.8)	24.6 (± 51.0)
Week 20	13.0 (± 22.2)	15.4 (± 32.0)	16.1 (± 31.2)	24.2 (± 46.1)
Week 24	13.0 (± 22.1)	18.7 (± 31.6)	18.8 (± 42.4)	24.6 (± 51.8)
Week 28	18.5 (± 36.9)	15.5 (± 24.6)	16.2 (± 31.2)	23.7 (± 45.3)
Week 32	17.8 (± 27.3)	17.7 (± 33.3)	21.4 (± 59.8)	21.0 (± 35.3)
Week 36	21.1 (± 54.8)	29.5 (± 84.0)	15.7 (± 30.5)	26.6 (± 51.2)
Week 40	14.9 (± 25.3)	16.5 (± 31.0)	14.7 (± 27.6)	23.2 (± 64.1)
Week 44	14.3 (± 23.7)	15.7 (± 32.6)	17.3 (± 33.5)	26.8 (± 58.6)
Week 48	15.6 (± 26.8)	17.9 (± 56.0)	15.3 (± 30.3)	24.8 (± 55.3)
Week 52	11.0 (± 17.9)	14.2 (± 27.5)	11.9 (± 20.5)	21.0 (± 55.7)

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:	
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 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.	
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.	

Serious adverse events	VC and LTS Period: Vehicle Cream BID	VC and LTS Period: Ruxolitinib 0.75% Cream BID	VC and LTS Period: Ruxolitinib 1.5% Cream BID
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 126 (1.59%)	9 / 300 (3.00%)	6 / 300 (2.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Nasal sinus cancer			
subjects affected / exposed	1 / 126 (0.79%)	0 / 300 (0.00%)	0 / 300 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Anaemia postoperative			

subjects affected / exposed	0 / 126 (0.00%)	1 / 300 (0.33%)	0 / 300 (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
Femur fracture			
subjects affected / exposed	0 / 126 (0.00%)	1 / 300 (0.33%)	0 / 300 (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
Humerus fracture			
subjects affected / exposed	0 / 126 (0.00%)	1 / 300 (0.33%)	0 / 300 (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
Pelvic fracture			
subjects affected / exposed	0 / 126 (0.00%)	1 / 300 (0.33%)	0 / 300 (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
Radius fracture			
subjects affected / exposed	0 / 126 (0.00%)	1 / 300 (0.33%)	0 / 300 (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
Rib fracture			
subjects affected / exposed	0 / 126 (0.00%)	1 / 300 (0.33%)	0 / 300 (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
Ulna fracture			
subjects affected / exposed	0 / 126 (0.00%)	1 / 300 (0.33%)	0 / 300 (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
Nervous system disorders			
Central nervous system lesion			
subjects affected / exposed	0 / 126 (0.00%)	1 / 300 (0.33%)	0 / 300 (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
Dizziness			

subjects affected / exposed	0 / 126 (0.00%)	0 / 300 (0.00%)	1 / 300 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 126 (0.00%)	0 / 300 (0.00%)	1 / 300 (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
Serositis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 300 (0.00%)	1 / 300 (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			
Acute abdomen			
subjects affected / exposed	0 / 126 (0.00%)	0 / 300 (0.00%)	1 / 300 (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
Colitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 300 (0.00%)	1 / 300 (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
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 300 (0.00%)	1 / 300 (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
Cholelithiasis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 300 (0.00%)	1 / 300 (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
Jaundice cholestatic			
subjects affected / exposed	0 / 126 (0.00%)	0 / 300 (0.00%)	1 / 300 (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

Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	1 / 126 (0.79%)	0 / 300 (0.00%)	0 / 300 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Substance-induced psychotic disorder			
subjects affected / exposed	0 / 126 (0.00%)	1 / 300 (0.33%)	0 / 300 (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			
Bronchitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 300 (0.00%)	1 / 300 (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
Cholecystitis infective			
subjects affected / exposed	0 / 126 (0.00%)	0 / 300 (0.00%)	1 / 300 (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
Pneumonia			
subjects affected / exposed	0 / 126 (0.00%)	2 / 300 (0.67%)	1 / 300 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypovolaemia			
subjects affected / exposed	0 / 126 (0.00%)	0 / 300 (0.00%)	1 / 300 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 126 (0.00%)	1 / 300 (0.33%)	0 / 300 (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

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 0.75% Cream BID	VC and LTS Period: Ruxolitinib 1.5% Cream BID
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 126 (7.94%)	52 / 300 (17.33%)	70 / 300 (23.33%)
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 126 (3.97%)	11 / 300 (3.67%)	16 / 300 (5.33%)
occurrences (all)	6	15	22
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	4 / 126 (3.17%)	27 / 300 (9.00%)	36 / 300 (12.00%)
occurrences (all)	4	36	41
Nasopharyngitis			
subjects affected / exposed	2 / 126 (1.59%)	18 / 300 (6.00%)	31 / 300 (10.33%)
occurrences (all)	2	22	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