



Clinical trial results:

A Double-Blind, Vehicle-Controlled, Randomized Withdrawal and Treatment Extension Study to Assess the Long-Term Efficacy and Safety of Ruxolitinib Cream in Participants With Vitiligo

Summary

EudraCT number	2020-000987-53
Trial protocol	DE NL FR PL BG
Global end of trial date	14 November 2022

Results information

Result version number	v1 (current)
This version publication date	28 May 2023
First version publication date	28 May 2023

Trial information

Trial identification

Sponsor protocol code	INCB 18424-308
-----------------------	----------------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Incyte Corporation
Sponsor organisation address	1801 Augustine Cutoff Drive, Wilmington, United States, 19803
Public contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.com
Scientific contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-002618-PIP02-20
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 November 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	14 November 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study was conducted to evaluate the duration of clinical response of ruxolitinib cream in participants with vitiligo.

Protection of trial subjects:

This study was to have been 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 was being conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 September 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Bulgaria: 30
Country: Number of subjects enrolled	Canada: 47
Country: Number of subjects enrolled	France: 24
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	Netherlands: 8
Country: Number of subjects enrolled	Poland: 89
Country: Number of subjects enrolled	Spain: 7
Country: Number of subjects enrolled	United States: 238
Worldwide total number of subjects	458
EEA total number of subjects	173

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)	58
Adults (18-64 years)	368
From 65 to 84 years	32
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 87 study centers in North America and Europe.

Pre-assignment

Screening details:

This randomized withdrawal and treatment-extension study (extension of treatment received in 2 parent studies: NCT04052425 or NCT04057573) was comprised of a 52-week extension treatment period and a 4-week safety follow-up period, starting 4 weeks (30 days) after the last application of study treatment or the last study visit.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort A: Vehicle cream BID

Arm description:

Participants who completed treatment and achieved $\geq 90\%$ improvement from Baseline in the Facial Vitiligo Area Scoring Index score (\geq F-VASI90) at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants were randomized to receive vehicle cream twice daily (BID) for 52 weeks. Participants who experienced relapse ($< 75\%$ improvement from Baseline in the F-VASI score [$<$ F-VASI75]) received open-label ruxolitinib 1.5% cream BID for the duration of the study.

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

Dosage and administration details:

Matching cream

Arm title	Cohort A: Ruxolitinib 1.5% cream BID
------------------	--------------------------------------

Arm description:

Participants who completed treatment and achieved \geq F-VASI90 at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants were randomized to receive ruxolitinib 1.5% cream BID for 52 weeks. Participants who experienced relapse ($<$ F-VASI75) received open-label ruxolitinib 1.5% cream BID for the duration of the study.

Arm type	Experimental
Investigational medicinal product name	ruxolitinib
Investigational medicinal product code	INCB018424
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

1.5% weight/weight (W/W) BID

Arm title	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID
------------------	---

Arm description:

Participants who completed treatment (vehicle cream BID for 24 weeks and ruxolitinib 1.5% BID for 28 weeks) and did not achieve \geq F-VASI90 at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants applied ruxolitinib 1.5% cream BID for 52 weeks.

Arm type	Experimental
Investigational medicinal product name	ruxolitinib
Investigational medicinal product code	INCB018424
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

1.5% weight/weight (W/W) BID

Arm title	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
------------------	--

Arm description:

Participants who completed treatment (ruxolitinib 1.5% BID for 52 weeks) and did not achieve \geq F-VASI90 at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants applied ruxolitinib 1.5% cream BID for 52 weeks.

Arm type	Experimental
Investigational medicinal product name	ruxolitinib
Investigational medicinal product code	INCB018424
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

1.5% weight/weight (W/W) BID

Number of subjects in period 1	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID
Started	58	58	118
Completed	41	50	92
Not completed	17	8	26
Missed Safety Follow-up Visit	-	-	1
Consent withdrawn by subject	14	5	18
Physician decision	-	-	1
Discontinued due to COVID-19 Pandemic	-	-	1
Adverse event, non-fatal	-	-	-
Pregnancy	-	-	2
Not Compliant with Protocol-specific Visit Window	-	-	-
Personal Reasons	-	-	-
Lost to follow-up	3	3	3
Site Closed Due to Noncompliance	-	-	-
Lack of efficacy	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Started	224
Completed	173
Not completed	51
Missed Safety Follow-up Visit	-
Consent withdrawn by subject	33
Physician decision	1
Discontinued due to COVID-19 Pandemic	-
Adverse event, non-fatal	1
Pregnancy	1
Not Compliant with Protocol-specific Visit Window	1
Personal Reasons	1
Lost to follow-up	10
Site Closed Due to Noncompliance	1
Lack of efficacy	1
Protocol deviation	1

Baseline characteristics

Reporting groups

Reporting group title	Cohort A: Vehicle cream BID
Reporting group description:	
Participants who completed treatment and achieved $\geq 90\%$ improvement from Baseline in the Facial Vitiligo Area Scoring Index score (\geq F-VASI90) at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants were randomized to receive vehicle cream twice daily (BID) for 52 weeks. Participants who experienced relapse ($< 75\%$ improvement from Baseline in the F-VASI score [$<$ F-VASI75]) received open-label ruxolitinib 1.5% cream BID for the duration of the study.	
Reporting group title	Cohort A: Ruxolitinib 1.5% cream BID
Reporting group description:	
Participants who completed treatment and achieved \geq F-VASI90 at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants were randomized to receive ruxolitinib 1.5% cream BID for 52 weeks. Participants who experienced relapse ($<$ F-VASI75) received open-label ruxolitinib 1.5% cream BID for the duration of the study.	
Reporting group title	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID
Reporting group description:	
Participants who completed treatment (vehicle cream BID for 24 weeks and ruxolitinib 1.5% BID for 28 weeks) and did not achieve \geq F-VASI90 at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants applied ruxolitinib 1.5% cream BID for 52 weeks.	
Reporting group title	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Reporting group description:	
Participants who completed treatment (ruxolitinib 1.5% BID for 52 weeks) and did not achieve \geq F-VASI90 at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants applied ruxolitinib 1.5% cream BID for 52 weeks.	

Reporting group values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID
Number of subjects	58	58	118
Age categorical			
Units: Subjects			
Adolescents (12-17 years)	4	8	10
Adults (18-64 years)	53	46	99
From 65-84 years	1	4	9
Age Continuous			
Units: years			
arithmetic mean	39.3	42.9	39.7
standard deviation	± 12.49	± 15.95	± 14.62
Sex: Female, Male			
Units: participants			
Female	31	33	61
Male	27	25	57
Race/Ethnicity, Customized			
Units: Subjects			
Asian	4	3	3
Black or African American	5	4	3
Native Hawaiian or Other Pacific Islander	1	0	0
Not Reported	2	1	3

White	42	48	107
Captured as Latino in Database	1	0	0
Persian	1	0	0
Indo-Caribbean	1	0	0
Jordanian	1	0	0
Brazilian	0	1	0
Guyana	0	1	0
American Indian or Alaska Native	0	0	0
Cape Verdean	0	0	1
Dominican Republic	0	0	1
Captured as Hispanic or Latino in Database	0	0	0
Iranian	0	0	0
Indian	0	0	0
North African	0	0	0
Middle Eastern	0	0	0
Arab//North-African	0	0	0
White/Black/Asian	0	0	0
Mexican	0	0	0
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	11	13	16
Not Hispanic or Latino	45	43	99
Not Reported	2	1	3
Unknown	0	0	0
Captured as Other in Database	0	1	0

Reporting group values	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID	Total	
Number of subjects	224	458	
Age categorial			
Units: Subjects			
Adolescents (12-17 years)	36	58	
Adults (18-64 years)	170	368	
From 65-84 years	18	32	
Age Continuous			
Units: years			
arithmetic mean	39.3		
standard deviation	± 16.45	-	
Sex: Female, Male			
Units: participants			
Female	129	254	
Male	95	204	
Race/Ethnicity, Customized			
Units: Subjects			
Asian	8	18	
Black or African American	11	23	
Native Hawaiian or Other Pacific Islander	1	2	
Not Reported	13	19	
White	180	377	

Captured as Latino in Database	0	1	
Persian	0	1	
Indo-Caribbean	0	1	
Jordanian	0	1	
Brazilian	0	1	
Guyana	0	1	
American Indian or Alaska Native	1	1	
Cape Verdean	1	2	
Dominican Republic	0	1	
Captured as Hispanic or Latino in Database	1	1	
Iranian	1	1	
Indian	1	1	
North African	1	1	
Middle Eastern	1	1	
Arab//North-African	1	1	
White/Black/Asian	1	1	
Mexican	2	2	
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	53	93	
Not Hispanic or Latino	157	344	
Not Reported	11	17	
Unknown	1	1	
Captured as Other in Database	2	3	

Subject analysis sets

Subject analysis set title	Cohort A: Vehicle cream BID to ruxolitinib 1.5% cream BID
Subject analysis set type	Full analysis

Subject analysis set description:

Participants who completed treatment and achieved $\geq 90\%$ improvement from Baseline in the Facial Vitiligo Area Scoring Index score ($\geq F\text{-VASI}90$) at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants were randomized to receive vehicle cream twice daily (BID) for 52 weeks. These participants experienced relapse ($< F\text{-VASI}75$) and received open-label ruxolitinib 1.5% cream BID for the duration of the study.

Subject analysis set title	Cohort B: Ruxolitinib 1.5% cream BID
Subject analysis set type	Full analysis

Subject analysis set description:

Participants who completed treatment (vehicle cream BID for 24 weeks and ruxolitinib 1.5% BID for 28 weeks or ruxolitinib 1.5% BID for 52 weeks) and did not achieve $\geq F\text{-VASI}90$ at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants applied ruxolitinib 1.5% cream BID for 52 weeks and had at least 1 post-Baseline pharmacokinetic (PK) assessment.

Subject analysis set title	Cohorts A and B: Ruxolitinib 1.5% cream BID
Subject analysis set type	Full analysis

Subject analysis set description:

Participants who completed treatment and achieved $\geq F\text{-VASI}90$ at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). Participants who completed treatment (vehicle cream BID for 24 weeks and ruxolitinib 1.5% BID for 28 weeks or ruxolitinib 1.5% BID for 52 weeks) and did not achieve $\geq F\text{-VASI}90$ at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants (58 from Cohort A; 289 from Cohort B) applied ruxolitinib 1.5% cream BID for 52 weeks And had at least 1 post-Baseline PK assessment.

Reporting group values	Cohort A: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream BID	Cohorts A and B: Ruxolitinib 1.5% cream BID
Number of subjects	23	293	347
Age categorical Units: Subjects			
Adolescents (12-17 years) Adults (18-64 years) From 65-84 years			
Age Continuous Units: years			
arithmetic mean	3		
standard deviation	±	±	±
Sex: Female, Male Units: participants			
Female Male			
Race/Ethnicity, Customized Units: Subjects			
Asian Black or African American Native Hawaiian or Other Pacific Islander Not Reported White Captured as Latino in Database Persian Indo-Caribbean Jordanian Brazilian Guyana American Indian or Alaska Native Cape Verdean Dominican Republic Captured as Hispanic or Latino in Database Iranian Indian North African Middle Eastern Arab//North-African White/Black/Asian Mexican			
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Not Reported Unknown Captured as Other in Database			

End points

End points reporting groups

Reporting group title	Cohort A: Vehicle cream BID
-----------------------	-----------------------------

Reporting group description:

Participants who completed treatment and achieved $\geq 90\%$ improvement from Baseline in the Facial Vitiligo Area Scoring Index score ($\geq F\text{-VASI}90$) at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants were randomized to receive vehicle cream twice daily (BID) for 52 weeks. Participants who experienced relapse ($< 75\%$ improvement from Baseline in the F-VASI score [$< F\text{-VASI}75$]) received open-label ruxolitinib 1.5% cream BID for the duration of the study.

Reporting group title	Cohort A: Ruxolitinib 1.5% cream BID
-----------------------	--------------------------------------

Reporting group description:

Participants who completed treatment and achieved $\geq F\text{-VASI}90$ at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants were randomized to receive ruxolitinib 1.5% cream BID for 52 weeks. Participants who experienced relapse ($< F\text{-VASI}75$) received open-label ruxolitinib 1.5% cream BID for the duration of the study.

Reporting group title	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID
-----------------------	---

Reporting group description:

Participants who completed treatment (vehicle cream BID for 24 weeks and ruxolitinib 1.5% BID for 28 weeks) and did not achieve $\geq F\text{-VASI}90$ at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants applied ruxolitinib 1.5% cream BID for 52 weeks.

Reporting group title	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
-----------------------	--

Reporting group description:

Participants who completed treatment (ruxolitinib 1.5% BID for 52 weeks) and did not achieve $\geq F\text{-VASI}90$ at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants applied ruxolitinib 1.5% cream BID for 52 weeks.

Subject analysis set title	Cohort A: Vehicle cream BID to ruxolitinib 1.5% cream BID
----------------------------	---

Subject analysis set type	Full analysis
---------------------------	---------------

Subject analysis set description:

Participants who completed treatment and achieved $\geq 90\%$ improvement from Baseline in the Facial Vitiligo Area Scoring Index score ($\geq F\text{-VASI}90$) at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants were randomized to receive vehicle cream twice daily (BID) for 52 weeks. These participants experienced relapse ($< F\text{-VASI}75$) and received open-label ruxolitinib 1.5% cream BID for the duration of the study.

Subject analysis set title	Cohort B: Ruxolitinib 1.5% cream BID
----------------------------	--------------------------------------

Subject analysis set type	Full analysis
---------------------------	---------------

Subject analysis set description:

Participants who completed treatment (vehicle cream BID for 24 weeks and ruxolitinib 1.5% BID for 28 weeks or ruxolitinib 1.5% BID for 52 weeks) and did not achieve $\geq F\text{-VASI}90$ at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants applied ruxolitinib 1.5% cream BID for 52 weeks and had at least 1 post-Baseline pharmacokinetic (PK) assessment.

Subject analysis set title	Cohorts A and B: Ruxolitinib 1.5% cream BID
----------------------------	---

Subject analysis set type	Full analysis
---------------------------	---------------

Subject analysis set description:

Participants who completed treatment and achieved $\geq F\text{-VASI}90$ at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). Participants who completed treatment (vehicle cream BID for 24 weeks and ruxolitinib 1.5% BID for 28 weeks or ruxolitinib 1.5% BID for 52 weeks) and did not achieve $\geq F\text{-VASI}90$ at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants (58 from Cohort A; 289 from Cohort B) applied ruxolitinib 1.5% cream BID for 52 weeks and had at least 1 post-Baseline PK assessment.

Primary: Time to relapse (defined as $< F\text{-VASI}75$)

End point title	Time to relapse (defined as $< F\text{-VASI}75$)
-----------------	---

End point description:

Relapse was defined as a loss of 75% improvement from Baseline in the Face Vitiligo Area Scoring Index score (F-VASI75) response, assessed as percentage improvement in the F-VASI score at Baseline (Day

1 of the parent study) to <75%. -9999, 9999=not estimable because there were too few events of loss of F-VASI75 response.

End point type	Primary
End point timeframe:	
up to Week 52 of Extension Study	

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	0 ^[1]	0 ^[2]
Units: days				
median (confidence interval 95%)	9999 (238.0 to 9999)	9999 (-9999 to 9999)	(to)	(to)

Notes:

[1] - Only participants in Cohort A were analyzed.

[2] - Only participants in Cohort A were analyzed.

Statistical analyses

Statistical analysis title	Time to relapse treatment/vehicle
Statistical analysis description:	
Cox regression model stratified by stratification factor (treatment assignment in the parent studies) was conducted to compare the difference in hazard rate between treatment and vehicle.	
Comparison groups	Cohort A: Vehicle cream BID v Cohort A: Ruxolitinib 1.5% cream BID
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0414
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.422
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.18
upper limit	0.99

Secondary: Time to loss of adequate response

End point title	Time to loss of adequate response
End point description:	
Loss of adequate response was defined as a loss of 90% improvement from Baseline in the F-VASI score (F-VASI90) response, assessed as percentage improvement in the F-VASI score at Baseline (Day 1 of the parent study) to <90%. -9999, 9999=not estimable because there were too few events of loss of F-VASI75 response.	
End point type	Secondary

End point timeframe:
up to Week 52 of Extension Study

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	0 ^[3]	0 ^[4]
Units: days				
median (confidence interval 95%)	195.0 (113.0 to 372.0)	9999 (-9999 to 9999)	(to)	(to)

Notes:

[3] - Only participants in Cohort A were analyzed.

[4] - Only participants in Cohort A were analyzed.

Statistical analyses

Statistical analysis title	Time to loss of response treatment/vehicle
Statistical analysis description:	
Cox regression model stratified by stratification factor (treatment assignment in the parent studies) was conducted to compare the difference in hazard rate between treatment and vehicle.	
Comparison groups	Cohort A: Vehicle cream BID v Cohort A: Ruxolitinib 1.5% cream BID
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.316
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.165
upper limit	0.606

Secondary: Percentage of participants achieving a $\geq 50\%$ improvement from Baseline in the Face Vitiligo Area Scoring Index (F-VASI50) score during the Extension Treatment Period

End point title	Percentage of participants achieving a $\geq 50\%$ improvement from Baseline in the Face Vitiligo Area Scoring Index (F-VASI50) score during the Extension Treatment Period
-----------------	---

End point description:

An F-VASI50 responder achieved at least 50% improvement from Baseline in F-VASI, measured by the percentage of vitiligo involvement (percentage of body surface area [BSA]) and the degree of depigmentation: 0% (no depigmentation), 10% (only specks of depigmentation), 25% (pigmented area exceeded depigmented area), 50% (depigmented and pigmented area was equal), 75% (depigmented area exceeded pigmented area), 90% (specks of pigment), or 100% (no pigment). The percentage of

BSA (hand unit) vitiligo involvement was estimated to the nearest 0.1% by the Investigator using the Palmar Method. The Investigator used his/her hand to mimic the participant's hand size to evaluate the percentage of BSA vitiligo involvement. F-VASI was then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site on the face and summing the values of all sites (possible range: 0-3; lower scores indicate increased improvement).

End point type	Secondary
End point timeframe:	
up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)	

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[5]	57 ^[6]	118 ^[7]	222 ^[8]
Units: percentage of participants				
number (confidence interval 95%)				
Week 52, n=57, 57, 118, 221	98.2 (90.6 to 100.0)	98.2 (90.6 to 100.0)	45.8 (36.6 to 55.2)	65.6 (58.9 to 71.9)
Week 56, n=56, 55, 108, 216	98.2 (90.4 to 100.0)	96.4 (87.5 to 99.6)	50.0 (40.2 to 59.8)	69.4 (62.8 to 75.5)
Week 60, n=48, 52, 107, 211	97.9 (88.9 to 99.9)	98.1 (89.7 to 100.0)	54.2 (44.3 to 63.9)	69.2 (62.5 to 75.4)
Week 64, n=43, 45, 108, 207	97.7 (87.7 to 99.9)	100.0 (92.1 to 100.0)	58.3 (48.5 to 67.7)	72.0 (65.3 to 78.0)
Week 68, n=41, 45, 107, 210	95.1 (83.5 to 99.4)	100.0 (92.1 to 100.0)	63.6 (53.7 to 72.6)	77.1 (70.9 to 82.6)
Week 80, n=30, 45, 99, 194	96.7 (82.8 to 99.9)	100.0 (92.1 to 100.0)	65.7 (55.4 to 74.9)	78.9 (72.4 to 84.4)
Week 92, n=23, 43, 94, 179	100.0 (85.2 to 100.0)	97.7 (87.7 to 99.9)	66.0 (55.5 to 75.4)	84.4 (78.2 to 89.3)
Week 104, n=23, 38, 93, 177	95.7 (78.1 to 99.9)	100.0 (90.7 to 100.0)	69.9 (59.5 to 79.0)	86.4 (80.5 to 91.1)

Notes:

[5] - Only participants with available data were analyzed.

[6] - Only participants with available data were analyzed.

[7] - Only participants with available data were analyzed.

[8] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a $\geq 75\%$ improvement from Baseline in the F-VASI (F-VASI75) score during the Extension Treatment Period

End point title	Percentage of participants achieving a $\geq 75\%$ improvement from Baseline in the F-VASI (F-VASI75) score during the Extension Treatment Period
-----------------	---

End point description:

An F-VASI75 responder achieved at least 75% improvement from Baseline in F-VASI, measured by the percentage of vitiligo involvement (percentage of BSA) and the degree of depigmentation: 0% (no depigmentation), 10% (only specks of depigmentation), 25% (pigmented area exceeded depigmented area), 50% (depigmented and pigmented area was equal), 75% (depigmented area exceeded pigmented area), 90% (specks of pigment), or 100% (no pigment). The percentage of BSA (hand unit)

vitiligo involvement was estimated to the nearest 0.1% by the Investigator using the Palmar Method. The Investigator used his/her hand to mimic the participant's hand size to evaluate the percentage of BSA vitiligo involvement. F-VASI was then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site on the face and summing the values of all sites (possible range: 0-3; lower scores indicate increased improvement).

End point type	Secondary
End point timeframe:	
up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)	

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[9]	57 ^[10]	118 ^[11]	222 ^[12]
Units: percentage of participants				
number (confidence interval 95%)				
Week 52, n=57, 57, 118, 221	98.2 (90.6 to 100.0)	98.2 (90.6 to 100.0)	16.1 (10.0 to 24.0)	30.8 (24.8 to 37.3)
Week 56, n=56, 55, 108, 216	96.4 (87.7 to 99.6)	96.4 (87.5 to 99.6)	23.1 (15.6 to 32.2)	34.7 (28.4 to 41.5)
Week 60, n=48, 52, 107, 211	95.8 (85.7 to 99.5)	90.4 (79.0 to 96.8)	29.0 (20.6 to 38.5)	40.8 (34.1 to 47.7)
Week 64, n=43, 45, 108, 207	95.3 (84.2 to 99.4)	97.8 (88.2 to 99.9)	30.6 (22.1 to 40.2)	43.5 (36.6 to 50.5)
Week 68, n=41, 45, 107, 210	87.8 (73.8 to 95.9)	100.0 (92.1 to 100.0)	34.6 (25.6 to 44.4)	48.6 (41.6 to 55.5)
Week 80, n=30, 45, 99, 194	90.0 (73.5 to 97.9)	100.0 (92.1 to 100.0)	43.4 (33.5 to 53.8)	54.6 (47.4 to 61.8)
Week 92, n=23, 43, 94, 179	100.0 (85.2 to 100.0)	97.7 (87.7 to 99.9)	47.9 (37.5 to 58.4)	60.3 (52.8 to 67.6)
Week 104, n=23, 38, 93, 177	95.7 (78.1 to 99.9)	97.4 (86.2 to 99.9)	47.3 (36.9 to 57.9)	66.1 (58.6 to 73.0)

Notes:

[9] - Only participants with available data were analyzed.

[10] - Only participants with available data were analyzed.

[11] - Only participants with available data were analyzed.

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

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a $\geq 90\%$ improvement from Baseline in the F-VASI (F-VASI90) score during the Extension Treatment Period

End point title	Percentage of participants achieving a $\geq 90\%$ improvement from Baseline in the F-VASI (F-VASI90) score during the Extension Treatment Period
-----------------	---

End point description:

An F-VASI90 responder achieved at least 90% improvement from Baseline in F-VASI, measured by the percentage of vitiligo involvement (percentage of BSA) and the degree of depigmentation: 0% (no depigmentation), 10% (only specks of depigmentation), 25% (pigmented area exceeded depigmented area), 50% (depigmented and pigmented area was equal), 75% (depigmented area exceeded pigmented area), 90% (specks of pigment), or 100% (no pigment). The percentage of BSA (hand unit)

vitiligo involvement was estimated to the nearest 0.1% by the Investigator using the Palmar Method. The Investigator used his/her hand to mimic the participant's hand size to evaluate the percentage of BSA vitiligo involvement. F-VASI was then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site on the face and summing the values of all sites (possible range: 0-3; lower scores indicate increased improvement).

End point type	Secondary
End point timeframe:	
up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)	

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[13]	57 ^[14]	118 ^[15]	222 ^[16]
Units: percentage of participants				
number (confidence interval 95%)				
Week 52, n=57, 57, 118, 221	98.2 (90.6 to 100.0)	96.5 (87.9 to 99.6)	0.0 (0.0 to 3.1)	2.3 (0.7 to 5.2)
Week 56, n=56, 55, 108, 216	89.3 (78.1 to 96.0)	94.5 (84.9 to 98.9)	3.7 (1.0 to 9.2)	8.3 (5.0 to 12.9)
Week 60, n=48, 52, 107, 211	83.3 (69.8 to 92.5)	86.5 (74.2 to 94.4)	8.4 (3.9 to 15.4)	15.2 (10.6 to 20.7)
Week 64, n=43, 45, 108, 207	72.1 (56.3 to 84.7)	93.3 (81.7 to 98.6)	11.1 (5.9 to 18.6)	15.5 (10.8 to 21.1)
Week 68, n=41, 45, 107, 210	68.3 (51.9 to 81.9)	95.6 (84.9 to 99.5)	12.1 (6.6 to 19.9)	22.4 (16.9 to 28.6)
Week 80, n=30, 45, 99, 194	80.0 (61.4 to 92.3)	97.8 (88.2 to 99.9)	22.2 (14.5 to 31.7)	30.4 (24.0 to 37.4)
Week 92, n=23, 43, 94, 179	78.3 (56.3 to 92.5)	93.0 (80.9 to 98.5)	24.5 (16.2 to 34.4)	32.4 (25.6 to 39.8)
Week 104, n=23, 38, 93, 177	69.6 (47.1 to 86.8)	92.1 (78.6 to 98.3)	28.0 (19.1 to 38.2)	33.9 (27.0 to 41.4)

Notes:

- [13] - Only participants with available data were analyzed.
- [14] - Only participants with available data were analyzed.
- [15] - Only participants with available data were analyzed.
- [16] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean F-VASI scores during the Extension Treatment Period

End point title	Mean F-VASI scores during the Extension Treatment Period
End point description:	

F-VASI was measured by the percentage of vitiligo involvement (percentage of BSA) and the degree of depigmentation: 0% (no depigmentation), 10% (only specks of depigmentation), 25% (pigmented area exceeded depigmented area), 50% (depigmented and pigmented area was equal), 75% (depigmented area exceeded pigmented area), 90% (specks of pigment), or 100% (no pigment). The percentage of BSA (hand unit) vitiligo involvement was estimated to the nearest 0.1% by the Investigator using the Palmar Method. The Investigator used his/her hand to mimic the participant's hand size to evaluate the percentage of BSA vitiligo involvement. F-VASI was then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site on the face and summing the

values of all sites (possible range: 0-3; lower scores indicate increased improvement).

End point type	Secondary
End point timeframe:	
up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)	

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[17]	57 ^[18]	118 ^[19]	222 ^[20]
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline, n=57, 57, 188, 222	0.86 (± 0.492)	0.99 (± 0.644)	0.88 (± 0.543)	0.91 (± 0.550)
Week 52, n=57, 57, 118, 221	0.05 (± 0.110)	0.07 (± 0.181)	0.51 (± 0.459)	0.39 (± 0.374)
Week 56, n=56, 55, 108, 216	0.05 (± 0.108)	0.07 (± 0.186)	0.50 (± 0.475)	0.38 (± 0.372)
Week 60, n=48, 52, 107, 211	0.06 (± 0.145)	0.09 (± 0.186)	0.45 (± 0.450)	0.35 (± 0.375)
Week 64, n=43, 45, 108, 207	0.08 (± 0.131)	0.08 (± 0.230)	0.43 (± 0.456)	0.33 (± 0.350)
Week 68, n=43, 45, 108, 207	0.11 (± 0.199)	0.04 (± 0.081)	0.40 (± 0.430)	0.31 (± 0.352)
Week 80, n=30, 45, 99, 194	0.05 (± 0.082)	0.04 (± 0.108)	0.36 (± 0.426)	0.27 (± 0.345)
Week 92, n=23, 43, 94, 179	0.04 (± 0.055)	0.04 (± 0.076)	0.38 (± 0.471)	0.23 (± 0.281)
Week 104, n=23, 38, 93, 177	0.06 (± 0.109)	0.04 (± 0.083)	0.37 (± 0.493)	0.21 (± 0.280)

Notes:

[17] - Only participants with available data were analyzed.

[18] - Only participants with available data were analyzed.

[19] - Only participants with available data were analyzed.

[20] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in F-VASI scores during the Extension Treatment Period

End point title	Change from Baseline in F-VASI scores during the Extension Treatment Period
-----------------	---

End point description:

F-VASI was measured by the percentage of vitiligo involvement (percentage of BSA) and the degree of depigmentation: 0% (no depigmentation), 10% (only specks of depigmentation), 25% (pigmented area exceeded depigmented area), 50% (depigmented and pigmented area was equal), 75% (depigmented area exceeded pigmented area), 90% (specks of pigment), or 100% (no pigment). The percentage of BSA (hand unit) vitiligo involvement was estimated to the nearest 0.1% by the Investigator using the Palmar Method. The Investigator used his/her hand to mimic the participant's hand size to evaluate the percentage of BSA vitiligo involvement. F-VASI was then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site on the face and summing the values of all sites (possible range: 0-3; lower scores indicate increased improvement). Change from Baseline was calculated as the post-Baseline value minus the Baseline value.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline; up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[21]	57 ^[22]	118 ^[23]	222 ^[24]
Units: scores on a scale				
arithmetic mean (standard deviation)				
Week 52, n=57, 57, 118, 221	-0.81 (± 0.464)	-0.92 (± 0.591)	-0.37 (± 0.346)	-0.51 (± 0.448)
Week 56, n=56, 55, 108, 216	-0.82 (± 0.492)	-0.90 (± 0.594)	-0.39 (± 0.370)	-0.54 (± 0.457)
Week 60, n=48, 52, 107, 211	-0.84 (± 0.447)	-0.87 (± 0.570)	-0.43 (± 0.402)	-0.55 (± 0.457)
Week 64, n=43, 45, 108, 207	-0.80 (± 0.442)	-0.87 (± 0.527)	-0.44 (± 0.423)	-0.58 (± 0.452)
Week 68, n=41, 45, 107, 210	-0.73 (± 0.316)	-0.86 (± 0.518)	-0.46 (± 0.437)	-0.61 (± 0.476)
Week 80, n=30, 45, 99, 194	-0.75 (± 0.360)	-0.86 (± 0.508)	-0.49 (± 0.471)	-0.64 (± 0.478)
Week 92, n=23, 43, 94, 179	-0.76 (± 0.341)	-0.87 (± 0.548)	-0.48 (± 0.531)	-0.69 (± 0.488)
Week 104, n=23, 38, 93, 177	-0.72 (± 0.380)	-0.92 (± 0.561)	-0.50 (± 0.557)	-0.68 (± 0.514)

Notes:

[21] - Only participants with available data were analyzed.

[22] - Only participants with available data were analyzed.

[23] - Only participants with available data were analyzed.

[24] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent change from Baseline in F-VASI scores during the Extension Treatment Period

End point title	Percent change from Baseline in F-VASI scores during the Extension Treatment Period
-----------------	---

End point description:

F-VASI was measured by the percentage of vitiligo involvement (percentage of BSA) and the degree of depigmentation: 0% (no depigmentation), 10% (only specks of depigmentation), 25% (pigmented area exceeded depigmented area), 50% (depigmented and pigmented area was equal), 75% (depigmented area exceeded pigmented area), 90% (specks of pigment), or 100% (no pigment). The percentage of BSA (hand unit) vitiligo involvement was estimated to the nearest 0.1% by the Investigator using the Palmar Method. The Investigator used his/her hand to mimic the participant's hand size to evaluate the percentage of BSA vitiligo involvement. F-VASI was then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site on the face and summing the values of all sites (possible range: 0-3; lower scores indicate increased improvement). Percentage change = ([post-BL value minus BL value]/BL value) X 100.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline (BL); up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[25]	57 ^[26]	118 ^[27]	222 ^[28]
Units: percentage change				
arithmetic mean (standard deviation)				
Week 52, n=57, 57, 118, 221	-94.45 (± 14.069)	-94.50 (± 8.990)	-44.32 (± 27.775)	-54.72 (± 31.006)
Week 56, n=56, 55, 108, 216	-93.79 (± 14.981)	-93.21 (± 12.573)	-46.19 (± 30.728)	-57.38 (± 31.256)
Week 60, n=48, 52, 107, 211	-93.85 (± 9.087)	-92.04 (± 13.198)	-50.55 (± 30.537)	-60.17 (± 30.147)
Week 64, n=43, 45, 108, 207	-89.64 (± 23.562)	-94.87 (± 8.079)	-52.32 (± 32.826)	-62.94 (± 27.427)
Week 68, n=41, 45, 107, 210	-87.98 (± 19.644)	-96.25 (± 4.633)	-55.27 (± 32.433)	-65.55 (± 30.388)
Week 80, n=30, 45, 99, 194	-93.24 (± 13.062)	-96.65 (± 4.683)	-58.60 (± 34.839)	-69.38 (± 29.091)
Week 92, n=23, 43, 94, 179	-95.77 (± 5.586)	-94.95 (± 10.366)	-55.44 (± 49.855)	-73.77 (± 25.490)
Week 104, n=23, 38, 93, 177	-90.53 (± 17.763)	-95.86 (± 7.213)	-56.53 (± 57.087)	-73.84 (± 31.780)

Notes:

[25] - Only participants with available data were analyzed.

[26] - Only participants with available data were analyzed.

[27] - Only participants with available data were analyzed.

[28] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a ≥50% improvement from Baseline in the Total Body Vitiligo Area Scoring Index (T-VASI50) score during the Extension Treatment Period

End point title	Percentage of participants achieving a ≥50% improvement from Baseline in the Total Body Vitiligo Area Scoring Index (T-VASI50) score during the Extension Treatment Period
-----------------	--

End point description:

A T-VASI50 responder achieved at least 50% improvement from Baseline in T-VASI, calculated with contributions from 6 sites. The percentage of vitiligo involvement was estimated in hand units (percentage of BSA estimated to nearest 0.1%) by the Investigator using the Palmar Method. The Investigator used his/her hand to mimic the participant's hand size to evaluate percent BSA vitiligo involvement. The degree of depigmentation for each site was estimated to the nearest percentage: 0% (no depigmentation present), 10% (only specks of depigmentation present), 25% (pigmented area exceeded depigmented area), 50% (depigmented and pigmented area was equal), 75% (depigmented area exceeded pigmented area), 90% (specks of pigment present), 100% (no pigment present). T-VASI was then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site and summing the values (range: 0-100; lower scores indicate increased improvement).

End point type	Secondary
----------------	-----------

End point timeframe:

up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[29]	57 ^[30]	118 ^[31]	222 ^[32]
Units: percentage of participants				
number (confidence interval 95%)				
Week 52, n=57, 57, 118, 221	80.7 (68.1 to 90.0)	71.9 (58.5 to 83.0)	16.9 (10.7 to 25.0)	42.5 (35.9 to 49.3)
Week 56, n=56, 55, 108, 216	76.8 (63.6 to 87.0)	72.7 (59.0 to 83.9)	16.7 (10.2 to 25.1)	45.8 (39.1 to 52.7)
Week 60, n=48, 52, 107, 211	83.3 (69.8 to 92.5)	75.0 (61.1 to 86.0)	19.6 (12.6 to 28.4)	49.8 (42.8 to 56.7)
Week 64, n=43, 45, 108, 207	74.4 (58.8 to 86.5)	82.2 (67.9 to 92.0)	21.3 (14.0 to 30.2)	50.7 (43.7 to 57.7)
Week 68, n=41, 45, 107, 210	70.7 (54.5 to 83.9)	84.4 (70.5 to 93.5)	29.9 (21.4 to 39.5)	54.3 (47.3 to 61.2)
Week 80, n=30, 45, 99, 194	80.0 (61.4 to 92.3)	86.7 (73.2 to 94.9)	39.4 (29.7 to 49.7)	57.7 (50.4 to 64.8)
Week 92, n=23, 43, 94, 179	73.9 (51.6 to 89.8)	86.0 (72.1 to 94.7)	48.9 (38.5 to 59.5)	61.5 (53.9 to 68.6)
Week 104, n=23, 38, 93, 177	60.9 (38.5 to 80.3)	89.5 (75.2 to 97.1)	54.8 (44.2 to 65.2)	63.8 (56.3 to 70.9)

Notes:

[29] - Only participants with available data were analyzed.

[30] - Only participants with available data were analyzed.

[31] - Only participants with available data were analyzed.

[32] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a $\geq 75\%$ improvement from Baseline in the T-VASI (T-VASI75) score during the Extension Treatment Period

End point title	Percentage of participants achieving a $\geq 75\%$ improvement from Baseline in the T-VASI (T-VASI75) score during the Extension Treatment Period
-----------------	---

End point description:

A T-VASI75 responder achieved at least 75% improvement from Baseline in T-VASI, calculated with contributions from 6 sites. The percentage of vitiligo involvement was estimated in hand units (percentage of BSA estimated to nearest 0.1%) by the Investigator using the Palmar Method. The Investigator used his/her hand to mimic the participant's hand size to evaluate percent BSA vitiligo involvement. The degree of depigmentation for each site was estimated to the nearest percentage: 0% (no depigmentation present), 10% (only specks of depigmentation present), 25% (pigmented area exceeded depigmented area), 50% (depigmented and pigmented area was equal), 75% (depigmented area exceeded pigmented area), 90% (specks of pigment present), 100% (no pigment present). T-VASI was then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site and summing the values (range: 0-100; lower scores indicate increased improvement).

End point type	Secondary
----------------	-----------

End point timeframe:

up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[33]	57 ^[34]	118 ^[35]	222 ^[36]
Units: percentage of participants				
number (confidence interval 95%)				
Week 52, n=57, 57, 118, 221	38.6 (26.0 to 52.4)	42.1 (29.1 to 55.9)	3.4 (0.9 to 8.5)	12.2 (8.2 to 17.3)
Week 56, n=56, 55, 108, 216	42.9 (29.7 to 56.8)	43.6 (30.3 to 57.7)	4.6 (1.5 to 10.5)	13.4 (9.2 to 18.7)
Week 60, n=48, 52, 107, 211	45.8 (31.4 to 60.8)	38.5 (25.3 to 53.0)	4.7 (1.5 to 10.6)	14.2 (9.8 to 19.7)
Week 64, n=43, 45, 108, 207	39.5 (25.0 to 55.6)	48.9 (33.7 to 64.2)	3.7 (1.0 to 9.2)	16.9 (12.1 to 22.7)
Week 68, n=41, 45, 107, 210	39.0 (24.2 to 55.5)	42.2 (27.7 to 57.8)	6.5 (2.7 to 13.0)	22.4 (16.9 to 28.6)
Week 80, n=30, 45, 99, 194	53.3 (34.3 to 71.7)	48.9 (33.7 to 64.2)	10.1 (5.0 to 17.8)	23.7 (17.9 to 30.3)
Week 92, n=23, 43, 94, 179	43.5 (23.2 to 65.5)	53.5 (37.7 to 68.8)	12.8 (6.8 to 21.2)	29.1 (22.5 to 36.3)
Week 104, n=23, 38, 93, 177	39.1 (19.7 to 61.5)	55.3 (38.3 to 71.4)	18.3 (11.0 to 27.6)	30.5 (23.8 to 37.9)

Notes:

[33] - Only participants with available data were analyzed.

[34] - Only participants with available data were analyzed.

[35] - Only participants with available data were analyzed.

[36] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a $\geq 90\%$ improvement from Baseline in the T-VASI (T-VASI90) score during the Extension Treatment Period

End point title	Percentage of participants achieving a $\geq 90\%$ improvement from Baseline in the T-VASI (T-VASI90) score during the Extension Treatment Period
-----------------	---

End point description:

A T-VASI90 responder achieved at least 90% improvement from Baseline in T-VASI, calculated with contributions from 6 sites. The percentage of vitiligo involvement was estimated in hand units (percentage of BSA estimated to nearest 0.1%) by the Investigator using the Palmar Method. The Investigator used his/her hand to mimic the participant's hand size to evaluate percent BSA vitiligo involvement. The degree of depigmentation for each site was estimated to the nearest percentage: 0% (no depigmentation present), 10% (only specks of depigmentation present), 25% (pigmented area exceeded depigmented area), 50% (depigmented and pigmented area was equal), 75% (depigmented area exceeded pigmented area), 90% (specks of pigment present), 100% (no pigment present). T-VASI was then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site and summing the values (range: 0-100; lower scores indicate increased improvement).

End point type	Secondary
----------------	-----------

End point timeframe:

up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[37]	57 ^[38]	118 ^[39]	222 ^[40]
Units: percentage of participants				
number (confidence interval 95%)				
Week 52, n=57, 57, 118, 221	12.3 (5.1 to 23.7)	12.3 (5.1 to 23.7)	0.0 (0.0 to 3.1)	2.3 (0.7 to 5.2)
Week 56, n=56, 55, 108, 216	12.5 (5.2 to 24.1)	14.5 (6.5 to 26.7)	0.0 (0.0 to 3.4)	3.2 (1.3 to 6.6)
Week 60, n=48, 52, 107, 211	16.7 (7.5 to 30.2)	17.3 (8.2 to 30.3)	0.0 (0.0 to 3.4)	3.8 (1.7 to 7.3)
Week 64, n=43, 45, 108, 207	20.9 (10.0 to 36.0)	20.0 (9.6 to 34.6)	0.0 (0.0 to 3.4)	2.9 (1.1 to 6.2)
Week 68, n=41, 45, 107, 210	22.0 (10.6 to 37.6)	20.0 (9.6 to 34.6)	0.9 (0.0 to 5.1)	4.3 (2.0 to 8.0)
Week 80, n=30, 45, 99, 194	20.0 (7.7 to 38.6)	20.0 (9.6 to 34.6)	1.0 (0.0 to 5.5)	6.7 (3.6 to 11.2)
Week 92, n=23, 43, 94, 179	21.7 (7.5 to 43.7)	20.9 (10.0 to 36.0)	2.1 (0.3 to 7.5)	8.9 (5.2 to 14.1)
Week 104, n=23, 38, 93, 177	21.7 (7.5 to 43.7)	23.7 (11.4 to 40.2)	3.2 (0.7 to 9.1)	9.6 (5.7 to 14.9)

Notes:

[37] - Only participants with available data were analyzed.

[38] - Only participants with available data were analyzed.

[39] - Only participants with available data were analyzed.

[40] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean T-VASI scores during the Extension Treatment Period

End point title	Mean T-VASI scores during the Extension Treatment Period
-----------------	--

End point description:

T-VASI was calculated with contributions from 6 sites. The percentage of vitiligo involvement was estimated in hand units (percentage of BSA estimated to nearest 0.1%) by the Investigator using the Palmar Method. The Investigator used his/her hand to mimic the participant's hand size to evaluate percent BSA vitiligo involvement. The degree of depigmentation for each site was estimated to the nearest percentage: 0% (no depigmentation present), 10% (only specks of depigmentation present), 25% (pigmented area exceeded depigmented area), 50% (depigmented and pigmented area was equal), 75% (depigmented area exceeded pigmented area), 90% (specks of pigment present), 100% (no pigment present). T-VASI was then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site and summing the values (range: 0-100; lower scores indicate increased improvement).

End point type	Secondary
----------------	-----------

End point timeframe:

up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[41]	57 ^[42]	118 ^[43]	222 ^[44]
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline, n=57, 57, 118, 222	6.06 (± 2.056)	6.27 (± 2.030)	6.69 (± 2.150)	6.74 (± 2.006)
Week 52, n=57, 57, 118, 221	2.38 (± 2.206)	2.36 (± 1.805)	5.25 (± 3.248)	3.90 (± 2.132)
Week 56, n=56, 55, 108, 216	2.39 (± 2.253)	2.31 (± 1.843)	5.06 (± 3.151)	3.80 (± 2.213)
Week 60, n=48, 52, 107, 211	2.21 (± 2.176)	2.30 (± 1.841)	4.86 (± 3.150)	3.58 (± 2.122)
Week 64, n=43, 45, 108, 207	2.33 (± 2.210)	1.94 (± 1.717)	4.85 (± 3.317)	3.57 (± 2.051)
Week 68, n=41, 45, 107, 210	2.45 (± 2.231)	1.76 (± 1.378)	4.51 (± 3.060)	3.43 (± 2.160)
Week 80, n=30, 45, 99, 194	2.05 (± 2.233)	1.73 (± 1.331)	4.18 (± 3.036)	3.18 (± 2.017)
Week 92, n=23, 43, 94, 179	2.17 (± 1.913)	1.65 (± 1.244)	4.12 (± 3.477)	3.04 (± 2.128)
Week 104, n=23, 38, 93, 177	2.86 (± 3.269)	1.54 (± 1.227)	4.00 (± 4.208)	2.92 (± 2.061)

Notes:

[41] - Only participants with available data were analyzed.

[42] - Only participants with available data were analyzed.

[43] - Only participants with available data were analyzed.

[44] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in T-VASI scores during the Extension Treatment Period

End point title	Change from Baseline in T-VASI scores during the Extension Treatment Period
-----------------	---

End point description:

T-VASI was calculated with contributions from 6 sites. The percentage of vitiligo involvement was estimated in hand units (percentage of BSA estimated to nearest 0.1%) by the Investigator using the Palmar Method. The Investigator used his/her hand to mimic the participant's hand size to evaluate percent BSA vitiligo involvement. The degree of depigmentation for each site was estimated to the nearest percentage: 0% (no depigmentation present), 10% (only specks of depigmentation present), 25% (pigmented area exceeded depigmented area), 50% (depigmented and pigmented area was equal), 75% (depigmented area exceeded pigmented area), 90% (specks of pigment present), 100% (no pigment present). T-VASI was then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site and summing the values (range: 0-100; lower scores indicate increased improvement). Change from Baseline=post-Baseline value minus the Baseline value.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline; up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[45]	57 ^[46]	118 ^[47]	222 ^[48]
Units: scores on a scale				
arithmetic mean (standard deviation)				
Week 52, n=57, 57, 118, 221	-3.68 (± 1.564)	-3.91 (± 1.526)	-1.45 (± 2.271)	-2.83 (± 1.938)
Week 56, n=56, 55, 108, 216	-3.71 (± 1.615)	-3.91 (± 1.503)	-1.69 (± 2.217)	-2.97 (± 2.086)
Week 60, n=48, 52, 107, 211	-3.79 (± 1.692)	-3.95 (± 1.585)	-1.83 (± 2.161)	-3.16 (± 2.027)
Week 64, n=43, 45, 108, 207	-3.60 (± 2.033)	-4.20 (± 1.569)	-1.84 (± 2.375)	-3.21 (± 2.060)
Week 68, n=41, 45, 107, 210	-3.44 (± 1.789)	-4.24 (± 1.534)	-2.21 (± 2.273)	-3.35 (± 2.143)
Week 80, n=30, 45, 99, 194	-3.79 (± 1.663)	-4.26 (± 1.519)	-2.49 (± 2.175)	-3.55 (± 2.109)
Week 92, n=23, 43, 94, 179	-3.85 (± 1.545)	-4.33 (± 1.673)	-2.61 (± 2.624)	-3.73 (± 2.246)
Week 104, n=23, 38, 93, 177	-3.05 (± 2.156)	-4.48 (± 1.702)	-2.71 (± 3.479)	-3.84 (± 2.151)

Notes:

[45] - Only participants with available data were analyzed.

[46] - Only participants with available data were analyzed.

[47] - Only participants with available data were analyzed.

[48] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent change from Baseline in T-VASI scores during the Extension Treatment Period

End point title	Percent change from Baseline in T-VASI scores during the Extension Treatment Period
-----------------	---

End point description:

T-VASI was calculated with contributions from 6 sites. The percentage of vitiligo involvement was estimated in hand units (percentage of BSA estimated to nearest 0.1%) by the Investigator using the Palmar Method. The Investigator used his/her hand to mimic the participant's hand size to evaluate percent BSA vitiligo involvement. The degree of depigmentation for each site was estimated to the nearest percentage: 0% (no depigmentation present), 10% (only specks of depigmentation present), 25% (pigmented area exceeded depigmented area), 50% (depigmented and pigmented area was equal), 75% (depigmented area exceeded pigmented area), 90% (specks of pigment present), 100% (no pigment present). T-VASI was then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site and summing the values (range: 0-100; lower scores indicate increased improvement). Percentage change = $([\text{post-BL value} - \text{BL value}] / \text{BL value}) \times 100$.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline; up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[49]	57 ^[50]	118 ^[51]	222 ^[52]
Units: percentage change				
arithmetic mean (standard deviation)				
Week 52, n=57, 57, 118, 221	-65.01 (± 23.969)	-64.95 (± 21.547)	-24.75 (± 2.271)	-42.14 (± 25.783)
Week 56, n=56, 55, 108, 216	-65.16 (± 24.916)	-65.69 (± 22.042)	-28.05 (± 30.487)	-43.91 (± 27.408)
Week 60, n=48, 52, 107, 211	-66.83 (± 26.478)	-65.58 (± 22.910)	-31.01 (± 28.944)	-47.00 (± 26.089)
Week 64, n=43, 45, 108, 207	-62.82 (± 33.328)	-70.44 (± 20.212)	-30.85 (± 32.898)	-46.96 (± 26.395)
Week 68, n=41, 45, 107, 210	-61.40 (± 29.204)	-71.89 (± 17.942)	-35.53 (± 32.135)	-49.41 (± 27.629)
Week 80, n=30, 45, 99, 194	-68.99 (± 26.870)	-72.21 (± 17.852)	-40.97 (± 30.033)	-52.48 (± 26.991)
Week 92, n=23, 43, 94, 179	-66.95 (± 24.885)	-72.55 (± 19.152)	-43.34 (± 34.425)	-55.00 (± 28.995)
Week 104, n=23, 38, 93, 177	-58.38 (± 35.533)	-74.66 (± 17.727)	-45.52 (± 41.968)	-56.96 (± 27.409)

Notes:

[49] - Only participants with available data were analyzed.

[50] - Only participants with available data were analyzed.

[51] - Only participants with available data were analyzed.

[52] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Facial Body Surface Area (F-BSA) scores during the Extension Treatment Period

End point title	Mean Facial Body Surface Area (F-BSA) scores during the Extension Treatment Period
-----------------	--

End point description:

F-BSA involvement was the proportion of the facial body surface area with vitiligo. The area "Face" was defined as including the area on the forehead to the original hairline, on the cheek to the jawline vertically to the jawline and laterally from the corner of the mouth to the tragus. The area "Face" did not include surface area of the lips, scalp, ears, or neck, but included the nose and eyelids. Body surface area assessment was performed by the Palmar Method. Body surface area was estimated to the nearest 0.1%. The approximate size of the participant's entire palmar surface (i.e., the palm plus 5 digits) was considered as 1% BSA, and the approximate size of the participant's thumb was considered as 0.1% BSA.

End point type	Secondary
----------------	-----------

End point timeframe:

up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[53]	57 ^[54]	118 ^[55]	222 ^[56]
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline, n=57, 57, 118, 222	0.92 (± 0.498)	1.10 (± 0.745)	1.01 (± 0.632)	1.02 (± 0.636)
Week 52, n=57, 57, 118, 221	0.18 (± 0.240)	0.27 (± 0.401)	0.81 (± 0.641)	0.70 (± 0.568)
Week 56, n=56, 55, 108, 216	0.18 (± 0.198)	0.27 (± 0.416)	0.77 (± 0.638)	0.67 (± 0.572)
Week 60, n=48, 51, 107, 211	0.20 (± 0.225)	0.25 (± 0.309)	0.73 (± 0.616)	0.63 (± 0.557)
Week 64, n=43, 45, 108, 207	0.20 (± 0.206)	0.20 (± 0.271)	0.71 (± 0.607)	0.61 (± 0.566)
Week 68, n=41, 45, 107, 210	0.22 (± 0.258)	0.16 (± 0.183)	0.67 (± 0.581)	0.57 (± 0.548)
Week 80, n=30, 45, 99, 194	0.12 (± 0.138)	0.15 (± 0.200)	0.62 (± 0.565)	0.55 (± 0.564)
Week 92, n=23, 43, 94, 179	0.10 (± 0.130)	0.15 (± 0.180)	0.64 (± 0.595)	0.49 (± 0.527)
Week 104, n=23, 38, 93, 177	0.13 (± 0.154)	0.15 (± 0.181)	0.62 (± 0.602)	0.47 (± 0.509)

Notes:

[53] - Only participants with available data were analyzed.

[54] - Only participants with available data were analyzed.

[55] - Only participants with available data were analyzed.

[56] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in F-BSA scores during the Extension Treatment Period

End point title	Change from Baseline in F-BSA scores during the Extension Treatment Period
-----------------	--

End point description:

F-BSA involvement was the proportion of the facial body surface area with vitiligo. The area "Face" was defined as including the area on the forehead to the original hairline, on the cheek to the jawline vertically to the jawline and laterally from the corner of the mouth to the tragus. The area "Face" did not include surface area of the lips, scalp, ears, or neck, but included the nose and eyelids. Body surface area assessment was performed by the Palmar Method. Body surface area was estimated to the nearest 0.1%. The approximate size of the participant's entire palmar surface (i.e., the palm plus 5 digits) was considered as 1% BSA, and the approximate size of the participant's thumb was considered as 0.1% BSA. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline; up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[57]	57 ^[58]	118 ^[59]	222 ^[60]
Units: scores on a scale				
arithmetic mean (standard deviation)				
Week 52, n=57, 57, 118, 221	-0.74 (± 0.402)	-0.83 (± 0.638)	-0.20 (± 0.313)	-0.31 (± 0.435)
Week 56, n=56, 55, 108, 216	-0.76 (± 0.458)	-0.82 (± 0.672)	-0.25 (± 0.345)	-0.35 (± 0.433)
Week 60, n=48, 51, 107, 211	-0.77 (± 0.441)	-0.80 (± 0.601)	-0.28 (± 0.364)	-0.38 (± 0.454)
Week 64, n=43, 45, 108, 207	-0.74 (± 0.446)	-0.83 (± 0.625)	-0.29 (± 0.417)	-0.41 (± 0.457)
Week 68, n=41, 45, 107, 210	-0.69 (± 0.345)	-0.86 (± 0.657)	-0.31 (± 0.425)	-0.45 (± 0.489)
Week 80, n=30, 45, 99, 194	-0.74 (± 0.381)	-0.87 (± 0.637)	-0.37 (± 0.494)	-0.48 (± 0.521)
Week 92, n=23, 43, 94, 179	-0.76 (± 0.374)	-0.87 (± 0.678)	-0.36 (± 0.558)	-0.54 (± 0.532)
Week 104, n=23, 38, 93, 177	-0.70 (± 0.400)	-0.93 (± 0.716)	-0.39 (± 0.604)	-0.54 (± 0.548)

Notes:

[57] - Only participants with available data were analyzed.

[58] - Only participants with available data were analyzed.

[59] - Only participants with available data were analyzed.

[60] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent change from Baseline in F-BSA scores during the Extension Treatment Period

End point title	Percent change from Baseline in F-BSA scores during the Extension Treatment Period
-----------------	--

End point description:

F-BSA involvement was the proportion of the facial body surface area with vitiligo. The area "Face" was defined as including the area on the forehead to the original hairline, on the cheek to the jawline vertically to the jawline and laterally from the corner of the mouth to the tragus. The area "Face" did not include surface area of the lips, scalp, ears, or neck, but included the nose and eyelids. Body surface area assessment was performed by the Palmar Method. Body surface area was estimated to the nearest 0.1%. The approximate size of the participant's entire palmar surface (i.e., the palm plus 5 digits) was considered as 1% BSA, and the approximate size of the participant's thumb was considered as 0.1% BSA. Percentage change = ([post-Baseline (BL) value minus BL value]/BL value) X 100.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline; up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[61]	57 ^[62]	118 ^[63]	222 ^[64]
Units: percentage change				
arithmetic mean (standard deviation)				
Week 52, n=57, 57, 118, 221	-80.75 (± 18.726)	-76.75 (± 23.470)	-22.15 (± 28.268)	-29.06 (± 36.354)
Week 56, n=56, 55, 108, 216	-80.23 (± 21.828)	-74.42 (± 35.048)	-26.20 (± 30.604)	-33.66 (± 33.944)
Week 60, n=48, 51, 107, 211	-79.20 (± 19.463)	-77.67 (± 20.946)	-30.04 (± 30.751)	-36.86 (± 33.289)
Week 64, n=43, 45, 108, 207	-75.92 (± 32.175)	-80.06 (± 22.142)	-30.67 (± 33.473)	-39.58 (± 31.992)
Week 68, n=41, 45, 107, 210	-77.11 (± 23.565)	-83.14 (± 21.999)	-32.60 (± 34.575)	-43.61 (± 32.549)
Week 80, n=30, 45, 99, 194	-84.55 (± 18.730)	-84.67 (± 22.014)	-36.79 (± 36.826)	-46.38 (± 34.407)
Week 92, n=23, 43, 94, 179	-87.81 (± 15.738)	-83.24 (± 23.746)	-34.05 (± 50.762)	-51.96 (± 31.510)
Week 104, n=23, 38, 93, 177	-82.87 (± 23.245)	-84.09 (± 22.920)	-35.82 (± 52.646)	-52.85 (± 32.983)

Notes:

[61] - Only participants with available data were analyzed.

[62] - Only participants with available data were analyzed.

[63] - Only participants with available data were analyzed.

[64] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Total Body Surface Area (T-BSA) scores during the Extension Treatment Period

End point title	Mean Total Body Surface Area (T-BSA) scores during the Extension Treatment Period
-----------------	---

End point description:

T-BSA involvement was the proportion of the body surface area with vitiligo. Body surface area assessment was performed by the Palmar Method. Body surface area was estimated to the nearest 0.1%. The approximate size of the participant's entire palmar surface (i.e., the palm plus 5 digits) was considered as 1% BSA, and the approximate size of the participant's thumb was considered as 0.1% BSA.

End point type	Secondary
----------------	-----------

End point timeframe:

up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[65]	57 ^[66]	118 ^[67]	222 ^[68]
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline, n=57, 57, 118, 222	6.79 (± 2.157)	6.85 (± 1.924)	7.42 (± 2.064)	7.49 (± 2.006)
Week 52, n=57, 57, 118, 221	4.09 (± 2.838)	4.20 (± 2.640)	6.95 (± 3.403)	5.96 (± 2.352)
Week 56, n=56, 55, 108, 216	4.11 (± 2.880)	4.13 (± 2.788)	6.73 (± 3.281)	5.81 (± 2.558)
Week 60, n=48, 51, 107, 211	3.77 (± 2.756)	4.09 (± 2.833)	6.61 (± 3.262)	5.64 (± 2.479)
Week 64, n=43, 45, 108, 207	3.98 (± 3.087)	3.49 (± 2.452)	6.67 (± 3.448)	5.64 (± 2.483)
Week 68, n=41, 45, 107, 210	3.92 (± 2.813)	3.27 (± 2.310)	6.46 (± 3.239)	5.51 (± 2.682)
Week 80, n=30, 45, 99, 194	3.72 (± 3.151)	3.18 (± 2.232)	6.09 (± 3.313)	5.27 (± 2.581)
Week 92, n=23, 43, 94, 179	3.94 (± 2.834)	3.04 (± 2.194)	5.96 (± 3.646)	5.15 (± 2.741)
Week 104, n=23, 38, 93, 177	4.56 (± 4.156)	2.93 (± 2.301)	5.91 (± 4.475)	5.07 (± 2.699)

Notes:

[65] - Only participants with available data were analyzed.

[66] - Only participants with available data were analyzed.

[67] - Only participants with available data were analyzed.

[68] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in T-BSA scores during the Extension Treatment Period

End point title	Change from Baseline in T-BSA scores during the Extension Treatment Period
-----------------	--

End point description:

T-BSA involvement was the proportion of the body surface area with vitiligo. Body surface area assessment was performed by the Palmar Method. Body surface area was estimated to the nearest 0.1%. The approximate size of the participant's entire palmar surface (i.e., the palm plus 5 digits) was considered as 1% BSA, and the approximate size of the participant's thumb was considered as 0.1% BSA. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline; up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[69]	57 ^[70]	118 ^[71]	222 ^[72]
Units: scores on a scale				
arithmetic mean (standard deviation)				

Week 52, n=57, 57, 118, 221	-2.70 (± 1.830)	-2.64 (± 1.906)	-0.47 (± 2.325)	-1.52 (± 1.711)
Week 56, n=56, 55, 108, 216	-2.74 (± 1.918)	-2.70 (± 1.983)	-0.73 (± 2.238)	-1.71 (± 2.059)
Week 60, n=48, 51, 107, 211	-2.95 (± 1.910)	-2.75 (± 2.195)	-0.80 (± 2.128)	-1.86 (± 1.978)
Week 64, n=43, 45, 108, 207	-2.73 (± 2.528)	-3.22 (± 1.883)	-0.73 (± 2.432)	-1.90 (± 2.052)
Week 68, n=41, 45, 107, 210	-2.73 (± 1.958)	-3.34 (± 1.922)	-0.98 (± 2.262)	-2.03 (± 2.180)
Week 80, n=30, 45, 99, 194	-3.05 (± 2.083)	-3.42 (± 1.809)	-1.31 (± 2.341)	-2.21 (± 2.169)
Week 92, n=23, 43, 94, 179	-3.03 (± 1.664)	-3.58 (± 1.938)	-1.49 (± 2.753)	-2.36 (± 2.380)
Week 104, n=23, 38, 93, 177	-2.18 (± 2.723)	-3.72 (± 2.075)	-1.52 (± 3.672)	-2.42 (± 2.307)

Notes:

[69] - Only participants with available data were analyzed.

[70] - Only participants with available data were analyzed.

[71] - Only participants with available data were analyzed.

[72] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent change from Baseline in T-BSA scores during the Extension Treatment Period

End point title	Percent change from Baseline in T-BSA scores during the Extension Treatment Period
-----------------	--

End point description:

T-BSA involvement was the proportion of the body surface area with vitiligo. Body surface area assessment was performed by the Palmar Method. Body surface area was estimated to the nearest 0.1%. The approximate size of the participant's entire palmar surface (i.e., the palm plus 5 digits) was considered as 1% BSA, and the approximate size of the participant's thumb was considered as 0.1% BSA. Percentage change = ([post-Baseline (BL) value minus BL value]/BL value) X 100.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline; up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[73]	57 ^[74]	118 ^[75]	222 ^[76]
Units: percentage change				
arithmetic mean (standard deviation)				
Week 52, n=57, 57, 118, 221	-43.81 (± 27.916)	-41.50 (± 28.747)	-8.54 (± 28.806)	-20.57 (± 23.042)
Week 56, n=56, 55, 108, 216	-44.22 (± 29.590)	-43.12 (± 29.489)	-11.96 (± 28.156)	-22.98 (± 26.032)

Week 60, n=48, 51, 107, 211	-47.61 (± 29.237)	-43.09 (± 31.608)	-13.40 (± 26.410)	-25.12 (± 25.564)
Week 64, n=43, 45, 108, 207	-43.29 (± 40.045)	-50.59 (± 27.166)	-12.00 (± 30.202)	-25.15 (± 26.860)
Week 68, n=41, 45, 107, 210	-44.53 (± 30.086)	-52.51 (± 26.921)	-15.01 (± 29.093)	-27.59 (± 28.476)
Week 80, n=30, 45, 99, 194	-50.51 (± 33.794)	-53.98 (± 25.682)	-20.22 (± 30.154)	-29.92 (± 27.996)
Week 92, n=23, 43, 94, 179	-48.53 (± 29.457)	-55.56 (± 26.401)	-22.84 (± 33.708)	-31.98 (± 30.805)
Week 104, n=23, 38, 93, 177	-40.84 (± 40.076)	-57.40 (± 27.898)	-24.26 (± 42.193)	-32.96 (± 29.907)

Notes:

[73] - Only participants with available data were analyzed.

[74] - Only participants with available data were analyzed.

[75] - Only participants with available data were analyzed.

[76] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a Vitiligo Noticeability Scale (VNS) score of 4 or 5 during the Extension Treatment Period

End point title	Percentage of participants achieving a Vitiligo Noticeability Scale (VNS) score of 4 or 5 during the Extension Treatment Period
-----------------	---

End point description:

The VNS is a patient-reported measure of vitiligo treatment success that is rated on a 5-point scale. The Baseline facial photograph was shown to the participants for reference, and a mirror was provided for the participants to assess the vitiligo on their face. The participant was asked to respond to the following query: Compared with before treatment, how noticeable is the vitiligo now? Responses: (1) more noticeable, (2) as noticeable, (3) slightly less noticeable, (4) a lot less noticeable, and (5) no longer noticeable.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline; up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57 ^[77]	57 ^[78]	118 ^[79]	222 ^[80]
Units: percentage of participants				
number (confidence interval 95%)				
Week 52, n=57, 57, 118, 221	49.1 (35.6 to 62.7)	42.1 (29.1 to 55.9)	11.9 (6.6 to 19.1)	35.3 (29.0 to 42.0)
Week 56, n=56, 55, 108, 216	48.2 (34.7 to 62.0)	34.5 (22.2 to 48.6)	20.4 (13.2 to 29.2)	30.1 (24.1 to 36.7)
Week 60, n=49, 52, 107, 210	46.9 (32.5 to 61.7)	28.8 (17.1 to 43.1)	19.6 (12.6 to 28.4)	27.6 (21.7 to 34.2)

Week 64, n=43, 45, 108, 206	53.5 (37.7 to 68.8)	37.8 (23.8 to 53.5)	23.1 (15.6 to 32.2)	28.2 (22.1 to 34.8)
Week 68, n=41, 45, 107, 210	46.3 (30.7 to 62.6)	46.7 (31.7 to 62.1)	20.6 (13.4 to 29.5)	33.8 (27.4 to 40.6)
Week 80, n=31, 45, 99, 195	38.7 (21.8 to 57.8)	42.2 (27.7 to 57.8)	28.3 (19.7 to 38.2)	32.8 (26.3 to 39.9)
Week 92, n=23, 43, 95, 180	39.1 (19.7 to 61.5)	37.2 (23.0 to 53.3)	28.4 (19.6 to 38.6)	41.1 (33.8 to 48.7)
Week 104, n=23, 38, 93, 178	56.5 (34.5 to 76.8)	50.0 (33.4 to 66.6)	30.1 (21.0 to 40.5)	43.3 (35.9 to 50.9)

Notes:

[77] - Only participants with available data were analyzed.

[78] - Only participants with available data were analyzed.

[79] - Only participants with available data were analyzed.

[80] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 52 in Dermatology Life Quality Index (DLQI) total score during the Extension Treatment Period

End point title	Change from Week 52 in Dermatology Life Quality Index (DLQI) total score during the Extension Treatment Period
-----------------	--

End point description:

The DLQI is a simple, 10-question validated questionnaire to measure how much the skin problem has affected the participant over the previous 7 days. Participants age ≥ 16 years answered the questionnaire with: (1) very much; (2) a lot; (3) a little; or (4) not at all. The questionnaire was analyzed under 6 headings: Symptoms and feelings (Questions 1 and 2); Daily activities (Questions 3 and 4); Leisure (Questions 5 and 6); Work and school (Question 7); Personal relations (Questions 8 and 9); and Treatment (Question 10). The total score range from 10 to 40; higher scores indicate higher quality of life. Change from Week 52 was calculated as the post-Week 52 value minus the Week 52 value.

End point type	Secondary
----------------	-----------

End point timeframe:

Week 52; up to up to Week 104 of Extension Study (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54 ^[81]	51 ^[82]	114 ^[83]	200 ^[84]
Units: scores on a scale				
arithmetic mean (standard deviation)				
Week 52, n=54, 51, 114, 200	2.87 (\pm 3.059)	4.10 (\pm 4.784)	3.69 (\pm 3.428)	3.53 (\pm 4.150)
Change from Week 52 at Week 56, n=53, 49, 104, 194	0.11 (\pm 2.054)	-0.47 (\pm 1.757)	-0.05 (\pm 2.138)	-0.22 (\pm 2.483)
Change from Week 52 at Week 60, n=46, 46, 103, 188	0.37 (\pm 2.388)	0.13 (\pm 2.227)	0.28 (\pm 2.491)	0.24 (\pm 2.929)
Change from Week 52 at Week 64, n=40, 40, 104, 184	0.35 (\pm 2.578)	0.18 (\pm 2.630)	-0.06 (\pm 2.712)	-0.14 (\pm 2.350)

Change from Week 52 at Week 68, n=38, 40, 103, 188	-0.08 (± 2.508)	-0.15 (± 2.202)	-0.17 (± 2.501)	0.08 (± 2.454)
Change from Week 52 at Week 80, n=29, 40, 95, 175	0.03 (± 3.006)	-0.23 (± 2.315)	-0.77 (± 2.871)	-0.13 (± 2.809)
Change from Week 52 at Week 92, n=22, 39, 91, 160	0.27 (± 2.354)	-0.23 (± 1.898)	-0.89 (± 2.383)	-0.22 (± 2.941)
Change from Week 52 at Week 104, n=21, 35, 89, 158	0.57 (± 2.135)	-0.40 (± 1.538)	-0.48 (± 2.277)	-0.06 (± 2.813)

Notes:

[81] - Only participants with available data were analyzed.

[82] - Only participants with available data were analyzed.

[83] - Only participants with available data were analyzed.

[84] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 52 in Children's Dermatology Life Quality Index (CDLQI) total score during the Extension Treatment Period

End point title	Change from Week 52 in Children's Dermatology Life Quality Index (CDLQI) total score during the Extension Treatment Period
-----------------	--

End point description:

The CDLQI is the youth/children's version of the DLQI. The DLQI is a simple, 10-question validated questionnaire to measure how much the skin problem has affected the participant over the previous 7 days. Participants age <16 years answered the questionnaire with: (1) very much; (2) a lot; (3) a little; or (4) not at all. The questionnaire was analyzed under 6 headings: Symptoms and feelings (Questions 1 and 2); Leisure (Questions 4, 5, and 6); School or holidays (Question 7); Personal relationships (Questions 3 and 8); Sleep (Question 9); and Treatment (Question 10). The total score ranges from 10 to 40; higher scores indicate higher quality of life. Change from Week 52 was calculated as the post-Week 52 value minus the Week 52 value. 9999=the mean and standard deviation cannot be calculated for a single participant.

End point type	Secondary
----------------	-----------

End point timeframe:

Week 52; up to Week 104 of Treatment Extension (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[85]	6 ^[86]	4 ^[87]	22 ^[88]
Units: scores on a scale				
arithmetic mean (standard deviation)				
Week 52, n=3, 6, 4, 22	1.67 (± 2.887)	1.00 (± 0.632)	1.25 (± 1.893)	2.32 (± 3.872)
Change from Week 52 at Week 56, n=3, 6, 4, 22	-1.00 (± 2.646)	-0.17 (± 0.753)	0.00 (± 0.816)	0.36 (± 1.989)
Change from Week 52 at Week 60, n=3, 6, 4, 22	0.00 (± 0.000)	-0.50 (± 0.548)	-0.50 (± 0.577)	-0.41 (± 2.108)
Change from Week 52 at Week 64, n=3, 5, 4, 22	-1.33 (± 2.309)	0.00 (± 0.707)	-1.00 (± 1.414)	-0.36 (± 1.399)

Change from Week 52 at Week 68, n=3, 5, 4, 22	-0.67 (± 1.155)	0.40 (± 1.140)	0.50 (± 0.577)	-0.23 (± 1.541)
Change from Week 52 at Week 80, n=2, 5, 4, 20	-2.00 (± 2.828)	-0.40 (± 0.548)	-0.75 (± 1.708)	0.15 (± 1.814)
Change from Week 52 at Week 92, n=1, 4, 4, 20	9999 (± 9999)	0.25 (± 1.258)	-0.25 (± 0.957)	0.70 (± 3.614)
Change from Week 52 at Week 104, n=2, 3, 4, 20	-0.50 (± 0.707)	-0.67 (± 1.155)	-1.25 (± 1.893)	-0.20 (± 4.086)

Notes:

[85] - Only participants with available data were analyzed.

[86] - Only participants with available data were analyzed.

[87] - Only participants with available data were analyzed.

[88] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

A TEAE was defined as any adverse event (AE) reported for the first time or the worsening of a pre-existing event after the first application of study drug in this study. An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug-related. An AE could therefore have been any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study treatment.

End point type	Secondary
----------------	-----------

End point timeframe:

up to approximately Week 108 (Week 52 was the first visit of this Treatment Extension study.)

End point values	Cohort A: Vehicle cream BID	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Vehicle cream BID to ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream to ruxolitinib 1.5% cream BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	58	118	224
Units: participants	21	32	59	114

End point values	Cohort A: Vehicle cream BID to ruxolitinib 1.5% cream BID			
Subject group type	Subject analysis set			
Number of subjects analysed	23			
Units: participants	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Trough plasma concentrations of ruxolitinib at Week 80 and Week 104

End point title	Trough plasma concentrations of ruxolitinib at Week 80 and Week 104 ^[89]
-----------------	---

End point description:

The steady-state plasma concentration was assessed. Pharmacokinetic blood samples could have been collected at any time prior to study drug application at the site at the Week 80 visit and at any time at the Week 104 (End of Trial) visit.

End point type	Secondary
----------------	-----------

End point timeframe:

Weeks 80 (predose); Week 104 (any time post-dose) (Week 52 was the first visit of this Treatment Extension study.)

Notes:

[89] - 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: Statistical analysis was not conducted for this endpoint.

End point values	Cohort A: Ruxolitinib 1.5% cream BID	Cohort B: Ruxolitinib 1.5% cream BID	Cohorts A and B: Ruxolitinib 1.5% cream BID	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	54 ^[90]	293 ^[91]	347 ^[92]	
Units: nanomolar				
arithmetic mean (standard deviation)				
12 to <18 years, n=8, 40, 48	7.28 (± 11.7)	5.56 (± 10.5)	5.85 (± 10.6)	
18 to <65 years, n=43, 229, 272	15.1 (± 19.5)	12.7 (± 17.2)	13.1 (± 17.6)	
≥65 years, n=3, 24, 27	13.0 (± 9.44)	25.7 (± 20.9)	24.3 (± 20.2)	
Overall, n=54, 293, 347	13.8 (± 18.1)	12.8 (± 17.4)	12.9 (± 17.5)	

Notes:

[90] - Only participants with available data were analyzed.

[91] - Only participants with available data were analyzed.

[92] - Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

up to approximately Week 108 (Week 52 was the first visit of this Treatment Extension study.)

Adverse event reporting additional description:

Treatment-emergent adverse events, defined as adverse events reported for the first time or the worsening of pre-existing events after the first application of study drug, have been reported.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	23.1
--------------------	------

Reporting groups

Reporting group title	Vehicle cream BID
-----------------------	-------------------

Reporting group description:

Participants who completed treatment and achieved $\geq 90\%$ improvement from Baseline in the Facial Vitiligo Area Scoring Index score (\geq F-VASI90) at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants were randomized to receive vehicle cream twice daily (BID) for 52 weeks. Participants who experienced relapse ($< 75\%$ improvement from Baseline in the F-VASI score [$<$ F-VASI75]) received open-label ruxolitinib 1.5% cream BID for the duration of the study.

Reporting group title	Total
-----------------------	-------

Reporting group description:

Total

Reporting group title	Ruxolitinib 1.5% cream BID
-----------------------	----------------------------

Reporting group description:

Participants who completed treatment and achieved \geq F-VASI90 at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants were randomized to receive ruxolitinib 1.5% cream BID for 52 weeks, or were randomized to receive vehicle cream BID but experienced relapse ($<$ F-VASI75) and received open-label ruxolitinib 1.5% cream BID for the duration of the study. Participants who completed treatment (vehicle cream BID for 24 weeks and ruxolitinib 1.5% BID for 28 weeks) and did not achieve \geq F-VASI90 at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants applied ruxolitinib 1.5% cream BID for 52 weeks. Participants who completed treatment (ruxolitinib 1.5% BID for 52 weeks) and did not achieve \geq F-VASI90 at Week 52 in either of 2 parent studies (NCT04052425 or NCT04057573). In this study, these participants applied ruxolitinib 1.5% cream BID for 52 weeks.

Serious adverse events	Vehicle cream BID	Total	Ruxolitinib 1.5% cream BID
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 58 (0.00%)	12 / 458 (2.62%)	12 / 423 (2.84%)
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)			
Uterine leiomyoma			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Spinal fracture			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Otosclerosis			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic prolapse			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystocele			

subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Bipolar I disorder			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Spinal osteoarthritis			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19 pneumonia			

subjects affected / exposed	0 / 58 (0.00%)	1 / 458 (0.22%)	1 / 423 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Vehicle cream BID	Total	Ruxolitinib 1.5% cream BID
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 58 (10.34%)	61 / 458 (13.32%)	55 / 423 (13.00%)
Infections and infestations			
COVID-19			
subjects affected / exposed	6 / 58 (10.34%)	61 / 458 (13.32%)	55 / 423 (13.00%)
occurrences (all)	6	63	57

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 September 2020	The primary purpose of this amendment was to accommodate the European Medicines Agency Pediatric Committee recommendation regarding the Dermatology Life Quality Index/Children's Dermatology Life Quality Index endpoint and to align the pharmacokinetic endpoints with those of parent studies INCB 18424-306 and INCB 18424-307.
10 November 2020	The main purpose of this amendment was to add language to the Protocol to inform sites of alternative strategies to guarantee continuity of the clinical trial conduct and oversight in response to the coronavirus disease 2019 (COVID-19) pandemic.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Data from participants at a single site (N = 2) were removed from all efficacy analyses performed on the ITT-Ext Population and FAS Cohort A owing to noncompliance with the Protocol in the parent study resulting in serious concerns with data quality.

Notes: