Clinical trial results:
A Phase 3 Multicenter, Double-Blind Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Adult Patients with Atopic Dermatitis

Summary

EudraCT number	2017-000873-35
Trial protocol	DE CZ HU AT ES PL FR DK IT
Global end of trial date	

Results information

Result version number	v1
This version publication date	02 June 2022
First version publication date	02 June 2022

Trial information

Trial identification

Sponsor protocol code	I4V-MC-JAHN

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03334435
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16587

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 8772854559,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	21 September 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 September 2020
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the long-term safety and efficacy of baricitinib in participants with atopic dermatitis.

Participants were enrolled in this study from the originating studies (JAHL, JAHM, JAIY) or were directly enrolled in the open-label arm.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy:

Background topical corticosteroids were permitted for use at the discretion of the investigator.

Evidence for comparator: -

Actual start date of recruitment	28 March 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 114
Country: Number of subjects enrolled	Australia: 109
Country: Number of subjects enrolled	Austria: 49
Country: Number of subjects enrolled	Czechia: 102
Country: Number of subjects enrolled	Denmark: 7
Country: Number of subjects enrolled	France: 34
Country: Number of subjects enrolled	Germany: 196
Country: Number of subjects enrolled	Hungary: 72
Country: Number of subjects enrolled	India: 31
Country: Number of subjects enrolled	Israel: 34
Country: Number of subjects enrolled	Italy: 68
Country: Number of subjects enrolled	Japan: 244
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 107
Country: Number of subjects enrolled	Mexico: 107
Country: Number of subjects enrolled	Poland: 132
Country: Number of subjects enrolled	Russian Federation: 51
Country: Number of subjects enrolled	Spain: 80
Country: Number of subjects enrolled	Switzerland: 18
Country: Number of subjects enrolled	Taiwan: 90

Worldwide total number of subjects	1645
EEA total number of subjects	740

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1602
From 65 to 84 years	43
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants who entered Study JAHN were classified as "Responders and Partial Responders (RPR): Investigator's Global Assessment (IGA) of (0,1, or 2) at entry to study JAHN and never rescued in originating study" or "Non-responders: those not meeting definition of RPR".

Pre-assignment

Screening details:

Participants who entered JAHN previously participated in JAHL, JAHM and JAIY and met the criteria for those studies, and, in the opinion of the investigator, there was unacceptable risk for the participants continued participation in the study.
OR
Participants who directly entered JAHN and met the criteria of JAHL, JAHM and JAIY.

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) and combination therapy study (JAIY) were randomized or assigned to this arm to receive placebo orally.

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

Dosage and administration details:

Administered orally

Arm title	Bari 1- milligram (mg)

Arm description:

Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) were randomized or assigned to this arm to receive Baricitinib 1 mg orally.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	
Other name	LY3009104
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally

Arm title	Bari 2-mg

Arm description:

Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) and combination study (JAIY) were randomized or assigned to this arm to receive Baricitinib 2 mg orally.

Arm type	Experimental

Investigational medicinal product name	Baricitinib
Investigational medicinal product code	
Other name	LY3009104
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally

Arm title	Bari 4-mg

Arm description:

Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) and combination study (JAIY) were randomized or assigned to this arm to receive Baricitinib 4 mg orally.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	
Other name	LY3009104
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally

Arm title	Bari 2-mg Open-Label Addendum

Arm description:

Participants were directly enrolled to this open-label arm to receive Baricitinib 2-mg orally.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	
Other name	LY3009104
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally

Number of subjects in period 1	Placebo	Bari 1- milligram (mg)	Bari 2-mg
Started	91	45	519
Completed	2	2	12
Not completed	89	43	507
Consent withdrawn by subject	11	4	38
Adverse event, non-fatal	2	1	9
Death	-	-	-
Not specified	-	1	3
Ongoing as of Week 52	70	32	379
Lost to follow-up	3	-	2
Lack of efficacy	3	5	76

Number of subjects in period 1	Bari 4-mg	Bari 2-mg Open-Label Addendum
Started	743	247

Completed	15	5
Not completed	728	242
Consent withdrawn by subject	42	20
Adverse event, non-fatal	23	13
Death	1	-
Not specified	2	1
Ongoing as of Week 52	519	146
Lost to follow-up	1	1
Lack of efficacy	140	61

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) and combination therapy study (JAIY) were randomized or assigned to this arm to receive placebo orally.	
Reporting group title	Bari 1- milligram (mg)
Reporting group description:	
Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) were randomized or assigned to this arm to receive Baricitinib 1 mg orally.	
Reporting group title	Bari 2-mg
Reporting group description:	
Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) and combination study (JAIY) were randomized or assigned to this arm to receive Baricitinib 2 mg orally.	
Reporting group title	Bari 4-mg
Reporting group description:	
Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) and combination study (JAIY) were randomized or assigned to this arm to receive Baricitinib 4 mg orally.	
Reporting group title	Bari 2-mg Open-Label Addendum
Reporting group description:	
Participants were directly enrolled to this open-label arm to receive Baricitinib 2-mg orally.	

Reporting group values	Placebo	Bari 1- milligram (mg)	Bari 2-mg
Number of subjects	91	45	519
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	35.2	33.5	34.2
standard deviation	± 14.06	± 8.49	± 12.69
Gender categorical Units: Subjects			
Female	44	16	206
Male	47	29	313
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	6	4	10
Asian	32	7	174

Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	0	0	1
White	48	32	315
More than one race	5	2	18
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
Argentina	6	2	36
Hungary	7	2	15
Czechia	3	3	22
Japan	11	3	89
Switzerland	0	1	5
India	5	0	7
Spain	2	1	27
Russia	0	1	9
Austria	2	0	12
South Korea	9	1	39
Taiwan	8	2	30
Denmark	0	0	0
Poland	10	7	45
Italy	7	4	16
Mexico	9	5	29
Israel	1	0	16
France	0	0	15
Australia	4	1	30
Germany	7	12	77

Reporting group values	Bari 4-mg	Bari 2-mg Open-Label Addendum	Total
Number of subjects	743	247	1645
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	35.6	34.9	
standard deviation	± 12.85	± 12.98	-
Gender categorical Units: Subjects			
Female	239	112	617
Male	504	135	1028

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	6	16	42
Asian	282	13	508
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	1	1	3
White	429	211	1035
More than one race	23	6	54
Unknown or Not Reported	2	0	2
Region of Enrollment Units: Subjects			
Argentina	46	24	114
Hungary	21	27	72
Czechia	46	28	102
Japan	141	0	244
Switzerland	9	3	18
India	19	0	31
Spain	26	24	80
Russia	13	28	51
Austria	23	12	49
South Korea	58	0	107
Taiwan	50	0	90
Denmark	0	7	7
Poland	70	0	132
Italy	26	15	68
Mexico	21	43	107
Israel	13	4	34
France	19	0	34
Australia	42	32	109
Germany	100	0	196

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) and combination therapy study (JAIY) were randomized or assigned to this arm to receive placebo orally.	
Reporting group title	Bari 1- milligram (mg)
Reporting group description:	
Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) were randomized or assigned to this arm to receive Baricitinib 1 mg orally.	
Reporting group title	Bari 2-mg
Reporting group description:	
Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) and combination study (JAIY) were randomized or assigned to this arm to receive Baricitinib 2 mg orally.	
Reporting group title	Bari 4-mg
Reporting group description:	
Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) and combination study (JAIY) were randomized or assigned to this arm to receive Baricitinib 4 mg orally.	
Reporting group title	Bari 2-mg Open-Label Addendum
Reporting group description:	
Participants were directly enrolled to this open-label arm to receive Baricitinib 2-mg orally.	
Subject analysis set title	RPR-Placebo
Subject analysis set type	Per protocol
Subject analysis set description:	
Responders or partial responders (RPR) [Investigator's Global Assessment (IGA) of (0,1, or 2) at entry to study JAHN and never rescued in originating study] participants from previous Baricitinib monotherapy studies-JAHL and JAHM and combination therapy study-JAIY were assigned to remain in this arm to receive placebo orally.	
Subject analysis set title	RPR-Bari 1-mg
Subject analysis set type	Per protocol
Subject analysis set description:	
RPR participants from previous Baricitinib monotherapy studies-JAHL and JAHM were assigned to remain in this arm to receive Baricitinib 1 mg orally.	
Subject analysis set title	RPR-Bari 2-mg
Subject analysis set type	Per protocol
Subject analysis set description:	
RPR participants from previous Baricitinib monotherapy studies-JAHL and JAHM and combination therapy study-JAIY were assigned to remain in this arm to receive Baricitinib 2 mg orally.	
Subject analysis set title	RPR-Bari 4-mg
Subject analysis set type	Per protocol
Subject analysis set description:	
RPR participants from previous Baricitinib monotherapy studies-JAHL and JAHM and combination therapy study-JAIY were assigned to remain in this arm to receive Baricitinib 4 mg orally.	
Subject analysis set title	Placebo
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) and combination therapy study (JAIY) were randomized or assigned to this arm to receive placebo orally.	
Subject analysis set title	Bari 2 mg
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) and combination therapy study (JAIY) were randomized or assigned to this arm to receive Baricitinib 2 mg orally.	

Subject analysis set title	Bari 4 mg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) and combination therapy study (JAIY) were randomized or assigned to this arm to receive Baricitinib 4 mg orally.ly.

Subject analysis set title	NR: Bari 1 mg to 2 mg
Subject analysis set type	Per protocol

Subject analysis set description:

Non-responder (NR) [those not meeting definition of RPR] participants from previous Baricitinib monotherapy studies-JAHL and JAHM who received Baricitinib 1 mg and were re-randomized to this arm to receive Baricitinib 2 mg orally.

Subject analysis set title	NR: Bari 1 mg to 4 mg
Subject analysis set type	Per protocol

Subject analysis set description:

NR participants from previous Baricitinib monotherapy studies-JAHL and JAHM who received Baricitinib 1 mg and were re-randomized to this arm to receive Baricitinib 4 mg orally.

Subject analysis set title	NR: Bari 2 mg to 2 mg
Subject analysis set type	Per protocol

Subject analysis set description:

NR participants from previous Baricitinib monotherapy studies-JAHL and JAHM and combination therapy study-JAIY who received Baricitinib 2 mg and were re-randomized to this arm to receive Baricitinib 2 mg orally.

Subject analysis set title	NR: Bari 2 mg to 4 mg
Subject analysis set type	Per protocol

Subject analysis set description:

NR participants from previous Baricitinib monotherapy studies-JAHL and JAHM and combination therapy study-JAIY who received Baricitinib 2 mg and were re-randomized to this arm to receive Baricitinib 4 mg orally.

Subject analysis set title	NR: Bari 4 mg to 4 mg
Subject analysis set type	Per protocol

Subject analysis set description:

NR participants from previous Baricitinib monotherapy studies-JAHL and JAHM and combination therapy study-JAIY who received Baricitinib 4 mg and were re-randomized to this arm to receive Baricitinib 4 mg orally.

Subject analysis set title	NR: Placebo to Bari 2 mg
Subject analysis set type	Per protocol

Subject analysis set description:

NR participants from previous Baricitinib monotherapy studies-JAHL and JAHM and combination therapy study-JAIY who received placebo and were re-randomized to this arm to receive Baricitinib 2 mg orally.

Subject analysis set title	NR: Placebo to Bari 4 mg
Subject analysis set type	Per protocol

Subject analysis set description:

NR participants from previous Baricitinib monotherapy studies-JAHL and JAHM and combination therapy study-JAIY who received placebo and were re-randomized to this arm to receive Baricitinib 4 mg orally.

Subject analysis set title	Bari 2-mg Open-Label Addendum
Subject analysis set type	Per protocol

Subject analysis set description:

Participants were directly enrolled to this open-label arm to receive Baricitinib 2-mg orally.

Subject analysis set title	Bari 1 mg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants from previous Baricitinib monotherapy studies (JAHL, JAHM) were randomized or assigned to this arm to receive Baricitinib 1 mg orally.

Primary: Responder and Partial Responders (RPR): Number of Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of Investigator's Global Assessment (IGA) 0 or 1

End point title	Responder and Partial Responders (RPR): Number of Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of Investigator's Global Assessment (IGA) 0 or 1[1]

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.

The results were analyzed using non-responder imputation (NRI). All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as IGA 0/1.

Modified Intent-to-treat Population: All RPR participants who received at least one dose of IP in JAHN. The participants here are from the previous Baricitinib monotherapy studies (JAHL and JAHM) as the results are presented as subsets of overall RPR population.

End point type	Primary

End point timeframe:

Weeks 16, 36 and 52

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The results were analyzed using non-responder imputation (NRI).

End point values	RPR-Placebo	RPR-Bari 1-mg	RPR-Bari 2-mg	RPR-Bari 4-mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	52	45	54	70
Units: participants				
number (not applicable)				
Week 16	19	21	32	34
Week 36	12	14	34	26
Week 52	15	16	27	28

Statistical analyses

No statistical analyses for this end point

Primary: RPR: Number of Participants From Combination Therapy Study (JAIY) Who Achieved a Response of IGA 0 or 1

End point title	RPR: Number of Participants From Combination Therapy Study (JAIY) Who Achieved a Response of IGA 0 or 1[2]

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.
The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as IGA 0/1.

Modified Intent-to-treat Population: All RPR participants who received at least one dose of IP in JAHN. The participants here are from the previous Baricitinib combination therapy study (JAIY) as the results

are presented as subsets of overall RPR population.

End point type	Primary

End point timeframe:

Weeks 16, 36, and 52

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The results were analyzed using non-responder imputation (NRI).

End point values	RPR-Placebo	RPR-Bari 2-mg	RPR-Bari 4-mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	34	53	63	
Units: participants				
number (not applicable)				
Week 16	16	24	20	
Week 36	14	13	19	
Week 52	10	16	20	

Statistical analyses

No statistical analyses for this end point

Secondary: RPR: Number of Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of IGA 0, 1 or 2

End point title	RPR: Number of Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of IGA 0, 1 or 2

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.
The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as IGA 0/1/2.

Modified Intent-to-treat Population: All RPR participants who received at least one dose of IP in JAHN. The participants here are from the previous Baricitinib monotherapy studies (JAHL and JAHM) as the results are presented as subsets of overall RPR population.

End point type	Secondary

End point timeframe:

Weeks 16, 36, and 52

End point values	RPR-Placebo	RPR-Bari 1-mg	RPR-Bari 2-mg	RPR-Bari 4-mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	52	45	54	70
Units: participants				
number (not applicable)				
Week 16	36	35	44	51
Week 36	25	27	44	41

Week 52	24	24	39	41

Statistical analyses

No statistical analyses for this end point

Secondary: RPR: Number of Participants From Combination Therapy Study (JAIY) Who Achieved a Response of IGA 0, 1, or 2

End point title	RPR: Number of Participants From Combination Therapy Study (JAIY) Who Achieved a Response of IGA 0, 1, or 2

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.
The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as IGA 0/1/2.

Modified Intent-to-treat Population: All RPR participants who received at least one dose of IP in JAHN. The participants here are from the previous Baricitinib combination therapy study (JAIY) as the results are presented as subsets of overall RPR population.

End point type	Secondary

End point timeframe:

Weeks 16, 36, and 52

End point values	Placebo	Bari 2 mg	Bari 4 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	34	53	63	
Units: participants				
number (not applicable)				
Week 16	24	39	40	
Week 36	19	26	33	
Week 52	17	29	33	

Statistical analyses

No statistical analyses for this end point

Secondary: Non Responders (NR): Number of Baricitinib NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of IGA 0, 1 or 2

End point title	Non Responders (NR): Number of Baricitinib NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of IGA 0, 1 or 2

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.
The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as IGA 0/1/2.

Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN. The participants here are from previous the Baricitinib monotherapy studies (JAHL and JAHM) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Weeks 16, 36 and 52

End point values	NR: Bari 1 mg to 2 mg	NR: Bari 1 mg to 4 mg	NR: Bari 2 mg to 2 mg	NR: Bari 2 mg to 4 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	87	81	84	78
Units: participants				
number (not applicable)				
Week 16	40	45	40	34
Week 36	35	35	37	38
Week 52	27	39	37	30

End point values	NR: Bari 4 mg to 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	156			
Units: participants				
number (not applicable)				
Week 16	63			
Week 36	61			
Week 52	64			

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Baricitinib NR Participants From Combination Therapy Study (JAIY) Who Achieved a Response of IGA 0, 1 or 2

End point title	NR: Number of Baricitinib NR Participants From Combination Therapy Study (JAIY) Who Achieved a Response of IGA 0, 1 or 2

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe

disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.
The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as IGA 0/1/2.

Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN. The participants here are from previous the previous Baricitinib combination therapy study (JAIY) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Weeks 16, 36, and 52

End point values	NR: Bari 2 mg to 2 mg	NR: Bari 2 mg to 4 mg	NR: Bari 4 mg to 4 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	21	39	
Units: participants				
number (not applicable)				
Week 16	7	12	12	
Week 36	8	9	8	
Week 52	9	9	11	

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Baricitinib NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of IGA 0 or 1

End point title	NR: Number of Baricitinib NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of IGA 0 or 1

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.
The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as IGA 0/1.

Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN. The participants here are from previous the Baricitinib monotherapy studies (JAHL and JAHM) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Weeks 16, 36, 52

End point values	NR: Bari 1 mg to 2 mg	NR: Bari 1 mg to 4 mg	NR: Bari 2 mg to 2 mg	NR: Bari 2 mg to 4 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	87	81	84	78
Units: participants				
number (not applicable)				
Week 16	12	19	13	14
Week 36	12	10	9	13
Week 52	11	10	16	12

End point values	NR: Bari 4 mg to 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	156			
Units: participants				
number (not applicable)				
Week 16	16			
Week 36	26			
Week 52	32			

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Baricitinib NR Participants From Combination Therapy Study (JAIY) Who Achieved a Response of IGA 0 or 1

End point title	NR: Number of Baricitinib NR Participants From Combination Therapy Study (JAIY) Who Achieved a Response of IGA 0 or 1

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.
The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as IGA 0/1.

Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN. The participants here are from previous the previous Baricitinib combination therapy study (JAIY) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Weeks 16, 36, and 52

End point values	NR: Bari 2 mg to 2 mg	NR: Bari 2 mg to 4 mg	NR: Bari 4 mg to 4 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	21	39	
Units: participants				
number (not applicable)				
Week 16	2	6	2	
Week 36	3	5	6	
Week 52	3	4	2	

Statistical analyses

No statistical analyses for this end point

Secondary: RPR: Number of Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of Eczema Area and Severity Index (EASI)75

End point title	RPR: Number of Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of Eczema Area and Severity Index (EASI)75

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.
The results were analyzed using NRI.
Modified Intent-to-treat Population: All RPR participants who received at least one dose of IP in JAHN.
The participants here are from the previous Baricitinib monotherapy studies (JAHL and JAHM) as the results are presented as subsets of overall RPR population.

End point type	Secondary

End point timeframe:

Weeks 16, 36, and 52

End point values	RPR-Placebo	RPR-Bari 1-mg	RPR-Bari 2-mg	RPR-Bari 4-mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	52	45	54	70
Units: participants				
number (not applicable)				
Week 16	22	28	38	45
Week 36	23	21	40	36
Week 52	20	23	35	36

Statistical analyses

No statistical analyses for this end point

Secondary: RPR: Number of Participants From Combination Therapy Study (JAIY) Who Achieved a Response of EASI 75

End point title	RPR: Number of Participants From Combination Therapy Study (JAIY) Who Achieved a Response of EASI 75

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score. The results were analyzed using NRI.
Modified Intent-to-treat Population: All RPR participants who received at least one dose of IP in JAHN. The participants here are from the previous Baricitinib combination therapy study (JAIY) as the results are presented as subsets of overall RPR population.

End point type	Secondary

End point timeframe:

Weeks 16, 36, and 52

End point values	RPR-Placebo	RPR-Bari 2-mg	RPR-Bari 4-mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	34	53	63	
Units: participants				
number (not applicable)				
Week 16	19	36	35	
Week 36	16	25	28	
Week 52	13	28	27	

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Baricitinib NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of EASI 75

End point title	NR: Number of Baricitinib NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of EASI 75

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score. The results were analyzed using NRI.
Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN. The participants here are from previous the Baricitinib monotherapy studies (JAHL and JAHM) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Weeks 16, 36, and 52

End point values	NR: Bari 1 mg to 2 mg	NR: Bari 1 mg to 4 mg	NR: Bari 2 mg to 2 mg	NR: Bari 2 mg to 4 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	87	81	84	78
Units: participants				
number (not applicable)				
Week 16	29	35	32	30
Week 36	28	25	26	35
Week 52	25	29	29	27

End point values	NR: Bari 4 mg to 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	156			
Units: participants				
number (not applicable)				
Week 16	42			
Week 36	48			
Week 52	52			

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Baricitinib NR Participants From Combination Therapy Study (JAIY) Who Achieved a Response of EASI 75

End point title	NR: Number of Baricitinib NR Participants From Combination Therapy Study (JAIY) Who Achieved a Response of EASI 75

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score. The results were analyzed using NRI.
Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN. The participants here are from previous the previous Baricitinib combination therapy study (JAIY) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Weeks 16, 36, and 52

End point values	NR: Bari 2 mg to 2 mg	NR: Bari 2 mg to 4 mg	NR: Bari 4 mg to 4 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	21	39	
Units: participants				
number (not applicable)				
Week 16	4	12	11	
Week 36	5	6	9	
Week 52	4	6	11	

Statistical analyses

No statistical analyses for this end point

Secondary: RPR: Number of Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved 4-Point Improvement Itch Numeric Rating Scale (NRS)

End point title	RPR: Number of Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved 4-Point Improvement Itch Numeric Rating Scale (NRS)

End point description:

The Itch NRS is a participant-administered, 11-point horizontal scale anchored at 0 and 10, with 0 representing "no itch" and 10 representing "worst itch imaginable." Overall severity of a participants itching is indicated by selecting the number, using a daily diary, that best describes the worst level of itching in the past 24 hours. The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as NRS.
Modified Intent-to-treat Population: All RPR participants who received at least one dose of IP in JAHN with Baseline Itch NRS Score >= 4. The participants here are from the previous Baricitinib monotherapy studies (JAHL and JAHM) as the results are presented as subsets of overall RPR population.

End point type	Secondary

End point timeframe:

Week 16

End point values	RPR-Placebo	RPR-Bari 1-mg	RPR-Bari 2-mg	RPR-Bari 4-mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	31	43	61
Units: participants				
number (not applicable)	14	8	14	25

Statistical analyses

No statistical analyses for this end point

Secondary: RPR: Number of Participants From Combination Therapy Study (JAIY) Who Achieved 4-Point Improvement in Itch NRS

End point title	RPR: Number of Participants From Combination Therapy Study (JAIY) Who Achieved 4-Point Improvement in Itch NRS

End point description:

The Itch NRS is a participant-administered, 11-point horizontal scale anchored at 0 and 10, with 0 representing "no itch" and 10 representing "worst itch imaginable." Overall severity of a participants itching is indicated by selecting the number, using a daily diary, that best describes the worst level of itching in the past 24 hours. The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as NRS.
Modified Intent-to-treat Population: All RPR participants who received at least one dose of IP in JAHN with Baseline Itch NRS Score >= 4. The participants here are from the previous Baricitinib combination therapy study (JAIY) as the results are presented as subsets of overall RPR population.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	Bari 2 mg	Bari 4 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	32	48	56	
Units: participants				
number (not applicable)	12	22	26	

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Baricitinib NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved 4-Point Improvement in Itch NRS

End point title	NR: Number of Baricitinib NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved 4-Point Improvement in Itch NRS

End point description:

The Itch NRS is a participant-administered, 11-point horizontal scale anchored at 0 and 10, with 0 representing "no itch" and 10 representing "worst itch imaginable." Overall severity of a participants itching is indicated by selecting the number, using a daily diary, that best describes the worst level of itching in the past 24 hours. The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as NRS.
Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN with Baseline Itch NRS Score >= 4. The participants here are from previous the Baricitinib monotherapy studies (JAHL and JAHM) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Week 16

End point values	NR: Bari 1 mg to 2 mg	NR: Bari 1 mg to 4 mg	NR: Bari 2 mg to 2 mg	NR: Bari 2 mg to 4 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	80	62	70	71
Units: participants				
number (not applicable)	16	24	17	22

End point values	NR: Bari 4 mg to 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	138			
Units: participants				
number (not applicable)	31			

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Baricitinib NR Participants From Combination Therapy Study (JAIY) Who Achieved 4-Point Improvement in Itch NRS

End point title	NR: Number of Baricitinib NR Participants From Combination Therapy Study (JAIY) Who Achieved 4-Point Improvement in Itch NRS

End point description:

The Itch NRS is a participant-administered, 11-point horizontal scale anchored at 0 and 10, with 0 representing "no itch" and 10 representing "worst itch imaginable." Overall severity of a participants itching is indicated by selecting the number, using a daily diary, that best describes the worst level of itching in the past 24 hours. The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as NRS.
Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN with Baseline Itch NRS Score >= 4. The participants here are from previous the previous Baricitinib combination therapy study (JAIY) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Week 16

End point values	NR: Bari 2 mg to 2 mg	NR: Bari 2 mg to 4 mg	NR: Bari 4 mg to 4 mg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	19	19	35	
Units: participants				
number (not applicable)	6	7	11	

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Placebo NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of IGA 0, 1 or 2

End point title	NR: Number of Placebo NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of IGA 0, 1 or 2

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.
The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as IGA 0/1/2.
Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN. The participants here are from previous the Baricitinib monotherapy studies (JAHL and JAHM) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 24, 52

End point values	NR: Placebo to Bari 2 mg	NR: Placebo to Bari 4 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	180	194		
Units: participants				
number (not applicable)				
Week 4	104	130		
Week 16	102	122		
Week 24	100	111		
Week 52	91	91		

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Placebo NR Participants From Combination Therapy Study (JAIY) Who Achieved a Response of IGA 0, 1 or 2

End point title	NR: Number of Placebo NR Participants From Combination Therapy Study (JAIY) Who Achieved a Response of IGA 0, 1 or 2

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.
The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as IGA 0/1/2.
Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN. The participants here are from previous the previous Baricitinib combination therapy study (JAIY) as the results are presented as subsets of overall NR population.

End point type	Secondary
End point timeframe: Weeks 4, 16, 24, 52	

End point values	NR: Placebo to Bari 2 mg	NR: Placebo to Bari 4 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	28		
Units: participants				
number (not applicable)				
Week 4	17	13		
Week 16	16	13		
Week 24	13	11		
Week 52	9	7		

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Placebo NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of IGA 0 or 1

End point title	NR: Number of Placebo NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of IGA 0 or 1

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as IGA 0/1.
Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN. The participants here are from previous the Baricitinib monotherapy studies (JAHL and JAHM) as the results are presented as subsets of overall NR population.

End point type	Secondary
End point timeframe: Weeks 4, 16, 24, 52	

End point values	NR: Placebo to Bari 2 mg	NR: Placebo to Bari 4 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	180	194		
Units: participants				
number (not applicable)				
Week 4	41	50		
Week 16	40	58		
Week 24	40	54		
Week 52	37	46		

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Placebo NR Participants From Combination Therapy Study (JAIY) Who Achieved a Response of IGA 0 or 1

End point title	NR: Number of Placebo NR Participants From Combination Therapy Study (JAIY) Who Achieved a Response of IGA 0 or 1

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their atopic dermatitis (AD), based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as IGA 0/1.
Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN. The participants here are from previous the previous Baricitinib combination therapy study (JAIY) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 24, 52

End point values	NR: Placebo to Bari 2 mg	NR: Placebo to Bari 4 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	28		
Units: participants				
number (not applicable)				
Week 4	0	4		
Week 16	2	7		
Week 24	4	5		
Week 52	2	3		

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Placebo NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of EASI 75

End point title	NR: Number of Placebo NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved a Response of EASI 75

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6

= 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.
The results were analyzed using NRI.
Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN. The participants here are from previous the Baricitinib monotherapy studies (JAHL and JAHM) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 24, 52

End point values	NR: Placebo to Bari 2 mg	NR: Placebo to Bari 4 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	180	194		
Units: participants				
number (not applicable)				
Week 4	70	91		
Week 16	79	104		
Week 24	81	88		
Week 52	74	75		

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Placebo NR Participants From Combination Therapy Study (JAIY) Who Achieved a Response of EASI 75

End point title	NR: Number of Placebo NR Participants From Combination Therapy Study (JAIY) Who Achieved a Response of EASI 75

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score. The results were analyzed using NRI.
Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN. The participants here are from previous the previous Baricitinib combination therapy study (JAIY) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 24, 52

End point values	NR: Placebo to Bari 2 mg	NR: Placebo to Bari 4 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	28		
Units: participants				
number (not applicable)				
Week 4	8	11		
Week 16	13	11		
Week 24	11	9		
Week 52	9	9		

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Placebo NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved 4-Point Improvement in Itch NRS

End point title	NR: Number of Placebo NR Participants From Monotherapy Studies (JAHL, JAHM) Who Achieved 4-Point Improvement in Itch NRS

End point description:

The Itch NRS is a participant-administered, 11-point horizontal scale anchored at 0 and 10, with 0 representing "no itch" and 10 representing "worst itch imaginable." Overall severity of a participants itching is indicated by selecting the number, using a daily diary, that best describes the worst level of itching in the past 24 hours. The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as NRS.
Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN with Baseline Itch NRS Score >= 4. The participants here are from previous the Baricitinib monotherapy studies (JAHL and JAHM) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Week 16

End point values	NR: Placebo to Bari 2 mg	NR: Placebo to Bari 4 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	165	171		
Units: participants				
number (not applicable)	56	61		

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Number of Placebo NR Participants From Combination Therapy Study (JAIY) Who Achieved 4-Point Improvement in Itch NRS

End point title	NR: Number of Placebo NR Participants From Combination

	Therapy Study (JAIY) Who Achieved 4-Point Improvement in Itch NRS

End point description:

The Itch NRS is a participant-administered, 11-point horizontal scale anchored at 0 and 10, with 0 representing "no itch" and 10 representing "worst itch imaginable." Overall severity of a participants itching is indicated by selecting the number, using a daily diary, that best describes the worst level of itching in the past 24 hours. The results were analyzed using NRI. All participants who either discontinued the study treatment or discontinued the study for any reason at any time were defined as non-responders for the NRI analysis for categorical variables such as NRS.
Modified Intent-to-treat Population: All NR participants who received at least one dose of IP in JAHN with Baseline Itch NRS Score >= 4. The participants here are from previous the previous Baricitinib combination therapy study (JAIY) as the results are presented as subsets of overall NR population.

End point type	Secondary

End point timeframe:

Week 16

End point values	NR: Placebo to Bari 2 mg	NR: Placebo to Bari 4 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	26		
Units: participants				
number (not applicable)	7	7		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline through Week 52

Adverse event reporting additional description:

All participants who received at least one dose of IP. The participants from open label arm were included in the Baricitinib 2-mg arm while reporting the safety data. Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Bari-2mg
Reporting group description: -	
Reporting group title	Bari-4mg
Reporting group description: -	
Reporting group title	Bari-1mg
Reporting group description: -	

Serious adverse events	Placebo	Bari-2mg	Bari-4mg
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 91 (5.49%)	33 / 766 (4.31%)	40 / 743 (5.38%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anaplastic large cell lymphoma t- and null-cell types			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bladder neoplasm			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

rectal cancer			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
thrombophlebitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	2 / 743 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vasculitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
uterine haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[1]	1 / 44 (2.27%)	0 / 318 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal			

disorders			
epistaxis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
contusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 91 (1.10%)	0 / 766 (0.00%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
facial bones fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			

alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament sprain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
limb injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple injuries			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
myocarditis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinus tachycardia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
supraventricular tachycardia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular extrasystoles			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
tinnitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinopathy proliferative			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rhegmatogenous retinal detachment			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
colitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
intestinal obstruction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatic failure			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
drug-induced liver injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 91 (1.10%)	0 / 766 (0.00%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic failure			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 91 (1.10%)	11 / 766 (1.44%)	9 / 743 (1.21%)
occurrences causally related to treatment / all	0 / 1	3 / 15	6 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dermatitis exfoliative			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
parakeratosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 91 (1.10%)	0 / 766 (0.00%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urticaria			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
calculus urinary			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal colic			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
bursitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
compartment syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteonecrosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess jaw			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis infective			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bacteraemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	2 / 743 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

eczema herpeticum			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	2 / 766 (0.26%)	6 / 743 (0.81%)
occurrences causally related to treatment / all	0 / 0	2 / 2	5 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
endophthalmitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteomyelitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
otitis externa			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
parainfluenzae virus infection			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 91 (1.10%)	0 / 766 (0.00%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 91 (1.10%)	0 / 766 (0.00%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psoas abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin bacterial infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

staphylococcal bacteraemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal skin infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
superinfection bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	2 / 743 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syphilis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 766 (0.00%)	1 / 743 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dairy intolerance			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 766 (0.13%)	0 / 743 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Bari-1mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 45 (2.22%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anaplastic large cell lymphoma t- and null-cell types			

alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bladder neoplasm				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
rectal cancer				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
squamous cell carcinoma				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
thrombophlebitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
vasculitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
anaphylactic reaction				
alternative dictionary used: MedDRA 22.1				

subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
uterine haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[1]	0 / 16 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
epistaxis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pulmonary embolism			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
contusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
facial bones fracture			
alternative dictionary used:			

MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
fall				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
foot fracture				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
joint dislocation				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ligament sprain				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
limb injury				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
meniscus injury				
alternative dictionary used: MedDRA 22.1				

subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
multiple injuries				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
road traffic accident				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tibia fracture				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
myocarditis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sinus tachycardia				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
supraventricular tachycardia				
alternative dictionary used: MedDRA 22.1				

subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ventricular extrasystoles			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
tinnitus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
retinopathy proliferative			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
rhegmatogenous retinal detachment			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
colitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
intestinal obstruction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pancreatic failure			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pancreatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
drug-induced liver injury				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hepatic failure				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
dermatitis atopic				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
dermatitis exfoliative				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
parakeratosis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
urticaria				
alternative dictionary used: MedDRA 22.1				

subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
calculus urinary			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
renal colic			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
renal failure			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
bursitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
compartment syndrome			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
intervertebral disc protrusion			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
osteonecrosis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
abscess jaw				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
appendicitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	1 / 45 (2.22%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
arthritis infective				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bacteraemia				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bronchitis				
alternative dictionary used: MedDRA 22.1				

subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cellulitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diverticulitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
eczema herpeticum				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
endophthalmitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
erysipelas				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
influenza				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

osteomyelitis				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
otitis externa				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
parainfluenzae virus infection				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
postoperative wound infection				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
psoas abscess				
alternative dictionary used: MedDRA 22.1				
subjects affected / exposed	0 / 45 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pyelonephritis				
alternative dictionary used: MedDRA 22.1				

subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
sinusitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
skin bacterial infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
staphylococcal skin infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
superinfection bacterial			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
syphilis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Metabolism and nutrition disorders			
dairy intolerance			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 45 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: The denominator was adjusted because it was a gender-specific event for females.

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

Non-serious adverse events	Placebo	Bari-2mg	Bari-4mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 91 (24.18%)	229 / 766 (29.90%)	243 / 743 (32.71%)
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	7 / 91 (7.69%)	48 / 766 (6.27%)	22 / 743 (2.96%)
occurrences (all)	7	60	37
General disorders and administration site conditions			
pyrexia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 91 (0.00%)	19 / 766 (2.48%)	19 / 743 (2.56%)
occurrences (all)	0	20	20
Infections and infestations			
herpes simplex			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	5 / 91 (5.49%)	20 / 766 (2.61%)	34 / 743 (4.58%)
occurrences (all)	5	31	41
nasopharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	11 / 91 (12.09%)	110 / 766 (14.36%)	128 / 743 (17.23%)
occurrences (all)	13	147	180
oral herpes			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	2 / 91 (2.20%)	34 / 766 (4.44%)	41 / 743 (5.52%)
occurrences (all)	3	49	55
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 91 (3.30%)	44 / 766 (5.74%)	45 / 743 (6.06%)
occurrences (all)	3	66	57

Non-serious adverse events	Bari-1mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 45 (35.56%)		
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences (all)	1		
General disorders and administration site conditions			
pyrexia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 45 (6.67%)		
occurrences (all)	3		
Infections and infestations			
herpes simplex			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences (all)	1		
nasopharyngitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	10 / 45 (22.22%)		
occurrences (all)	18		
oral herpes			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences (all)	2		
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 November 2019	Substantial Amendment (c): - Included an additional six visits to reflect the 2-year extension to the study. - Updated discontinuation criteria for VTEs requiring permanent discontinuation after one VTE instead of two. - Added discontinuation criteria to reflect the possibility of study termination following potential approval or dismissal of Baricitinib for atopic dermatitis within a given country. - Removed leukotriene inhibitors and allergen immunotherapy from prohibited medications.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported