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	12 July 2023

Results information

Result version number	v2 (current)
This version publication date	27 July 2024
First version publication date	02 June 2022
Version creation reason	• New data added to full data set LPV Results

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	Final
Date of interim/final analysis	12 July 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 July 2023
Was the trial ended prematurely?	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	Hungary: 72
Country: Number of subjects enrolled	Czechia: 102
Country: Number of subjects enrolled	Japan: 244
Country: Number of subjects enrolled	Switzerland: 18
Country: Number of subjects enrolled	India: 31
Country: Number of subjects enrolled	Spain: 80
Country: Number of subjects enrolled	Russian Federation: 51
Country: Number of subjects enrolled	Austria: 49
Country: Number of subjects enrolled	Korea, Republic of: 107
Country: Number of subjects enrolled	Taiwan: 90
Country: Number of subjects enrolled	Denmark: 7
Country: Number of subjects enrolled	Poland: 132
Country: Number of subjects enrolled	Italy: 68
Country: Number of subjects enrolled	Mexico: 107
Country: Number of subjects enrolled	Israel: 34
Country: Number of subjects enrolled	France: 34

Country: Number of subjects enrolled	Australia: 109
Country: Number of subjects enrolled	Germany: 196
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 (NR): those not meeting definition of RPR".

Pre-assignment

Screening details:

The study has two treatment periods: Treatment period 1, from Week 0 up to Week 52, and Treatment period 2, from Week 52 through Week 200 (which included randomized withdrawal and downtitration substudy).

Period 1

Period 1 title	Treatment Period 1: Week 0 to Week 52
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 (Baricitinib) 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	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered Baricitinib 1 mg 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	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered Baricitinib 2 mg 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	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered Baricitinib 4 mg 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 (Baricitinib) 1-milligram (mg)	Bari 2-mg
Started	91	45	519
Completed	2	2	12
Not completed	89	43	507
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	11	4	38
Adverse event, non-fatal	2	1	9
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
Adverse event, serious fatal	1	-
Consent withdrawn by subject	42	20
Adverse event, non-fatal	23	13
Not specified	2	1
Ongoing as of Week 52	519	146
Lost to follow-up	1	1
Lack of efficacy	140	61

Period 2

Period 2 title	Treatment Period 2: Week 52 to Week 200
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	No
Arm title	2 mg Bari to Placebo Substudy

Arm description:

Participants who received Baricitinib 2 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive placebo orally.

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

Dosage and administration details:

Administered placebo orally.

Arm title	2 mg Bari to 1 mg Bari Substudy

Arm description:

Participants who received Baricitinib 2 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive Baricitinib 1 mg orally.

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

Dosage and administration details:

Administered Baricitinib 1 mg orally.

Arm title	2 mg Bari to 2 mg Bari Substudy

Arm description:

Participants who received Baricitinib 2 mg at the start of Study JAHN were rerandomized at week 52 or

assigned to this arm to receive Baricitinib 2 mg orally.

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

Dosage and administration details:

Administered Baricitinib 2 mg orally.

Arm title	4 mg Bari to Placebo Substudy

Arm description:

Participants who received Baricitinib 4 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive placebo orally.

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

Dosage and administration details:

Administered orally.

Arm title	4 mg Bari to 2 mg Bari Substudy

Arm description:

Participants who received Baricitinib 4 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive Baricitinib 2 mg orally.

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

Dosage and administration details:

Administered Baricitinib 2 mg orally.

Arm title	4 mg Bari to 4 mg Bari Substudy

Arm description:

Participants who received Baricitinib 4 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive Baricitinib 4 mg orally.

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

Dosage and administration details:

Administered Baricitinib 4 mg orally.

Arm title	Placebo to Placebo Non-substudy

Arm description:

Participants who received placebo at the start of Study JAHN who were not eligible to enter the substudy at week 52 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	1 mg Bari to 1 mg Bari Non-substudy

Arm description:

Participants who received Baricitinib 1 mg at the start of Study JAHN who were not eligible to enter the substudy at week 52 assigned to this arm to receive Baricitinib 1 mg orally.

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

Dosage and administration details:

Administered Baricitinib 1 mg orally.

Arm title	2 mg Bari to 2 mg Bari Non-substudy

Arm description:

Participants who received Baricitinib 2 mg at the start of Study JAHN who were not eligible to enter the substudy at week 52 assigned to this arm to receive Baricitinib 2 mg orally.

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

Dosage and administration details:

Administered Baricitinib 2 mg orally.

Arm title	4 mg Bari to 4 mg Bari Non-substudy

Arm description:

Participants who received Baricitinib 4 mg at the start of Study JAHN who were not eligible to enter the substudy at week 52 assigned to this arm to receive Baricitinib 4 mg orally.

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

Dosage and administration details:

Administered Baricitinib 4 mg orally.

Number of subjects in period 2	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy	2 mg Bari to 2 mg Bari Substudy
Started	92	91	92
Completed	29	40	38
Not completed	63	51	54
Adverse event, serious fatal	1	-	-
Physician Decision	1	-	-
Withdrawal due to Caregiver Circumstances	-	-	-
Study Terminated by Sponsor	17	21	17
Sponsor decision	-	-	1
Consent withdrawn by subject	23	15	20
Adverse event, non-fatal	6	1	2
Protocol deviation	1	1	-
Pregnancy	-	-	-
Lost to follow-up	-	2	2
Physician is retiring	1	1	1
Lack of efficacy	13	10	11
Protocol deviation	-	-	-

Number of subjects in period 2	4 mg Bari to Placebo Substudy	4 mg Bari to 2 mg Bari Substudy	4 mg Bari to 4 mg Bari Substudy
Started	84	84	84
Completed	34	40	35
Not completed	50	44	49
Adverse event, serious fatal	-	-	-
Physician Decision	-	-	1
Withdrawal due to Caregiver Circumstances	-	-	-
Study Terminated by Sponsor	19	15	17
Sponsor decision	1	-	1
Consent withdrawn by subject	17	10	11
Adverse event, non-fatal	2	3	9
Protocol deviation	-	-	-
Pregnancy	-	-	-
Lost to follow-up	3	1	1
Physician is retiring	1	3	1
Lack of efficacy	7	12	8
Protocol deviation	-	-	-

Number of subjects in period 2	Placebo to Placebo Non-substudy	1 mg Bari to 1 mg Bari Non-substudy	2 mg Bari to 2 mg Bari Non-substudy
Started	70	32	249

Completed	28	23	60
Not completed	42	9	189
Adverse event, serious fatal	-	-	-
Physician Decision	-	-	-
Withdrawal due to Caregiver Circumstances	1	-	1
Study Terminated by Sponsor	16	3	66
Sponsor decision	3	1	-
Consent withdrawn by subject	8	-	41
Adverse event, non-fatal	3	2	11
Protocol deviation	1	1	2
Pregnancy	1	-	1
Lost to follow-up	1	-	4
Physician is retiring	1	-	-
Lack of efficacy	7	2	63
Protocol deviation	-	-	-

Number of subjects in period 2	4 mg Bari to 4 mg Bari Non-substudy
Started	264
Completed	68
Not completed	196
Adverse event, serious fatal	1
Physician Decision	1
Withdrawal due to Caregiver Circumstances	-
Study Terminated by Sponsor	70
Sponsor decision	-
Consent withdrawn by subject	32
Adverse event, non-fatal	13
Protocol deviation	-
Pregnancy	1
Lost to follow-up	4
Physician is retiring	-
Lack of efficacy	72
Protocol deviation	2

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 (Baricitinib) 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 (Baricitinib) 1-milligram (mg)	Bari 2-mg
Number of subjects	91	45	519
Age categorical Units: Subjects			
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
Ethnicity (NIH/OMB Units: Subjects			
HISPANIC OR LATINO	15	10	70
NOT HISPANIC OR LATINO	57	32	332
UNKNOWN OR NOT REPORTED	19	3	117

Reporting group values	Bari 4-mg	Bari 2-mg Open-Label Addendum	Total
Number of subjects	743	247	1645
Age categorical Units: Subjects			
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
Ethnicity (NIH/OMB Units: Subjects			
HISPANIC OR LATINO	87	72	254
NOT HISPANIC OR LATINO	467	165	1053
UNKNOWN OR NOT REPORTED	189	10	338

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 (Baricitinib) 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 title	2 mg Bari to Placebo Substudy
Reporting group description:	
Participants who received Baricitinib 2 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive placebo orally.	
Reporting group title	2 mg Bari to 1 mg Bari Substudy
Reporting group description:	
Participants who received Baricitinib 2 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive Baricitinib 1 mg orally.	
Reporting group title	2 mg Bari to 2 mg Bari Substudy
Reporting group description:	
Participants who received Baricitinib 2 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive Baricitinib 2 mg orally.	
Reporting group title	4 mg Bari to Placebo Substudy
Reporting group description:	
Participants who received Baricitinib 4 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive placebo orally.	
Reporting group title	4 mg Bari to 2 mg Bari Substudy
Reporting group description:	
Participants who received Baricitinib 4 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive Baricitinib 2 mg orally.	
Reporting group title	4 mg Bari to 4 mg Bari Substudy
Reporting group description:	
Participants who received Baricitinib 4 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive Baricitinib 4 mg orally.	
Reporting group title	Placebo to Placebo Non-substudy
Reporting group description:	
Participants who received placebo at the start of Study JAHN who were not eligible to enter the substudy at week 52 assigned to this arm to receive placebo orally.	
Reporting group title	1 mg Bari to 1 mg Bari Non-substudy
Reporting group description:	
Participants who received Baricitinib 1 mg at the start of Study JAHN who were not eligible to enter the substudy at week 52 assigned to this arm to receive Baricitinib 1 mg orally.	

Reporting group title	2 mg Bari to 2 mg Bari Non-substudy

Reporting group description:

Participants who received Baricitinib 2 mg at the start of Study JAHN who were not eligible to enter the substudy at week 52 assigned to this arm to receive Baricitinib 2 mg orally.

Reporting group title	4 mg Bari to 4 mg Bari Non-substudy

Reporting group description:

Participants who received Baricitinib 4 mg at the start of Study JAHN who were not eligible to enter the substudy at week 52 assigned to this arm to receive Baricitinib 4 mg orally.

Subject analysis set title	RPR-Placebo
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 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 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 were assigned to remain in this arm to receive Baricitinib 4 mg orally.

Subject analysis set title	NR: Bari 1 mg to 2 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 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 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 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 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 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 who received placebo and were re-randomized to this arm to receive Baricitinib 4 mg orally.

Primary: Responder and Partial Responders (RPR): Percentage 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): Percentage 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.

Analysis population description (APD): 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: Only descriptive statistics along with a confidence interval are performed for this end point.

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: Percentage of participants				
number (confidence interval 95%)				
Week 16	36.5 (24.8 to 50.1)	46.7 (32.9 to 60.9)	59.3 (46.0 to 71.3)	48.6 (37.2 to 60.0)
Week 36	23.1 (13.7 to 36.1)	31.1 (19.5 to 45.7)	63.0 (49.6 to 74.6)	37.1 (26.8 to 48.9)
Week 52	28.8 (18.3 to 42.3)	35.6 (23.2 to 50.2)	50.0 (37.1 to 62.9)	40.0 (29.3 to 51.7)

Statistical analyses

No statistical analyses for this end point

Primary: RPR: Percentage of Participants from combination therapy study (JAIY)

who achieved a response of IGA 0 or 1

End point title	RPR: Percentage 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.

APD: 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: Only descriptive statistics along with a confidence interval are performed for this end point.

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: Percentage of participants				
number (confidence interval 95%)				
Week 16	47.1 (31.5 to 63.3)	45.3 (32.7 to 58.5)	31.7 (21.6 to 44.0)	
Week 36	41.2 (26.4 to 57.8)	24.5 (14.9 to 37.6)	30.2 (20.2 to 42.4)	
Week 52	29.4 (16.8 to 46.2)	30.2 (19.5 to 43.5)	31.7 (21.6 to 44.0)	

Statistical analyses

No statistical analyses for this end point

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

End point title	RPR: Percentage 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.

APD: 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: Percentage of participants				
number (confidence interval 95%)				
Week 16	69.2 (55.7 to 80.1)	77.8 (63.7 to 87.5)	81.5 (69.2 to 89.6)	72.9 (61.5 to 81.9)
Week 36	48.1 (35.1 to 61.3)	60.0 (45.5 to 73.0)	81.5 (69.2 to 89.6)	58.6 (46.9 to 69.4)
Week 52	46.2 (33.3 to 59.5)	53.3 (39.1 to 67.1)	58.6 (46.9 to 69.4)	58.6 (46.9 to 69.4)

Statistical analyses

No statistical analyses for this end point

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

End point title	RPR: Percentage 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.

APD: 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: Percentage of participants				
number (confidence interval 95%)				
Week 16	70.6 (53.8 to 83.2)	73.6 (60.4 to 83.6)	63.5 (51.1 to 74.3)	
Week 36	55.9 (39.5 to 71.1)	49.1 (36.1 to 62.1)	52.4 (40.3 to 64.2)	

Week 52	50.0 (34.1 to 65.9)	54.7 (41.5 to 67.3)	52.4 (40.3 to 64.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Non Responders (NR): Percentage 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): Percentage 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.

APD: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: Percentage of participants				
number (confidence interval 95%)				
Week 16	46.0 (35.9 to 56.4)	55.6 (44.7 to 65.9)	47.6 (37.3 to 58.2)	43.6 (33.1 to 54.6)
Week 36	40.2 (30.6 to 50.7)	43.2 (33.0 to 54.1)	44.0 (33.9 to 54.7)	48.7 (37.9 to 59.6)
Week 52	31.0 (22.3 to 41.4)	48.1 (37.6 to 58.9)	44.0 (33.9 to 54.7)	38.5 (28.4 to 49.6)

End point values	NR: Bari 4 mg to 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	156			
Units: Percentage of participants				
number (confidence interval 95%)				

Week 16	40.4 (33.0 to 48.2)			
Week 36	39.1 (31.8 to 46.9)			
Week 52	41.0 (33.6 to 48.9)			

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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.

APD: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: Percentage of participants				
number (confidence interval 95%)				
Week 16	35.0 (18.1 to 56.7)	57.1 (36.5 to 75.5)	30.8 (18.6 to 46.4)	
Week 36	40.0 (21.9 to 61.3)	42.9 (24.5 to 63.5)	20.5 (10.8 to 35.5)	
Week 52	45.0 (25.8 to 65.8)	42.9 (24.5 to 63.5)	28.2 (16.5 to 43.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: NR: Percentage of Baricitinib NR Participants From Monotherapy Studies

(JAHL, JAHM) Who Achieved a Response of IGA 0 or 1

End point title	NR: Percentage 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.

APD: 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: Percentage of participants				
number (confidence interval 95%)				
Week 16	13.8 (8.1 to 22.6)	23.5 (15.6 to 33.8)	15.5 (9.3 to 24.7)	17.9 (11.0 to 27.9)
Week 36	13.8 (8.1 to 22.6)	12.3 (6.8 to 21.3)	10.7 (5.7 to 19.1)	16.7 (10.0 to 26.5)
Week 52	12.6 (7.2 to 21.2)	12.3 (6.8 to 21.3)	19.0 (12.1 to 28.7)	15.4 (9.0 to 25.0)

End point values	NR: Bari 4 mg to 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	156			
Units: Percentage of participants				
number (confidence interval 95%)				
Week 16	10.3 (6.4 to 16.0)			
Week 36	16.7 (11.6 to 23.3)			
Week 52	20.5 (14.9 to 27.5)			

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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.

APD: 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: Percentage of participants				
number (confidence interval 95%)				
Week 16	10.0 (2.8 to 30.1)	28.6 (13.8 to 50.0)	5.1 (1.4 to 16.9)	
Week 36	15.0 (5.2 to 36.0)	23.8 (10.6 to 45.1)	15.4 (7.2 to 29.7)	
Week 52	15.0 (5.2 to 36.0)	19.0 (7.7 to 40.0)	5.1 (1.4 to 16.9)	

Statistical analyses

No statistical analyses for this end point

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

End point title	RPR: Percentage 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). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.
APD: 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 Weeks
Results were analyzed using NRI. Participants who either discontinued study treatment or discontinued study for any reason at any time were defined as non-responders for the NRI analysis for categorical variable such as EASI 75

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: Percentage of participants				
number (confidence interval 95%)				
Week 16	42.3 (29.9 to 55.8)	62.2 (47.6 to 74.9)	70.4 (57.2 to 80.9)	64.3 (52.6 to 74.5)
Week 36	44.2 (31.6 to 57.7)	46.7 (32.9 to 60.9)	74.1 (61.1 to 83.9)	51.4 (40.0 to 62.8)
Week 52	38.5 (26.5 to 52.0)	51.1 (37.0 to 65.0)	64.8 (51.5 to 76.2)	51.4 (40.0 to 62.8)

Statistical analyses

No statistical analyses for this end point

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

End point title	RPR: Percentage 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). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD: 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

Results were analyzed using NRI. Participants who either discontinued 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 EASI75

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: Percentage of participants				
number (confidence interval 95%)				
Week 16	55.9 (39.5 to 71.1)	67.9 (54.5 to 78.9)	55.6 (43.3 to 67.2)	
Week 36	47.1 (31.5 to 63.3)	47.2 (34.4 to 60.3)	44.4 (32.8 to 56.7)	
Week 52	38.2 (23.9 to 55.0)	52.8 (39.7 to 65.6)	42.9 (31.4 to 55.1)	

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD: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
Results were analyzed using NRI. Participants who either discontinued 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 EASI75.

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: Percentage of participants				
number (confidence interval 95%)				
Week 16	33.3 (24.3 to 43.8)	43.2 (33.0 to 54.1)	38.1 (28.4 to 48.8)	38.5 (28.4 to 49.6)
Week 36	32.2 (23.3 to 42.6)	30.9 (21.9 to 41.6)	31.0 (22.1 to 41.5)	44.9 (34.3 to 55.9)

Week 52	28.7 (20.3 to 29.0)	35.8 (26.2 to 46.7)	34.5 (25.2 to 45.2)	34.6 (25.0 to 45.7)

End point values	NR: Bari 4 mg to 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	156			
Units: Percentage of participants				
number (confidence interval 95%)				
Week 16	26.9 (20.6 to 34.4)			
Week 36	30.8 (24.1 to 38.4)			
Week 52	33.3 (26.4 to 41.1)			

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD: 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
Results were analyzed using NRI. Participants who either discontinued 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 EASI 75.

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: Percentage of participants				
number (confidence interval 95%)				
Week 16	20.8 (8.1 to 41.6)	57.2 (36.5 to 75.5)	28.2 (16.5 to 43.8)	
Week 36	25.0 (11.2 to 46.9)	28.6 (13.8 to 50.0)	23.1 (12.6 to 38.3)	
Week 52	20.0 (8.1 to 41.6)	28.6 (13.8 to 50.0)	28.2 (16.5 to 43.8)	

Statistical analyses

No statistical analyses for this end point

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

End point title	RPR: Percentage 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.
APD: 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: Percentage of participants				
number (confidence interval 95%)	32.6 (20.5 to 47.5)	25.8 (13.7 to 43.2)	32.6 (20.5 to 47.5)	41.0 (29.5 to 53.5)

Statistical analyses

No statistical analyses for this end point

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

End point title	RPR: Percentage 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.

APD: 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	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	32	48	56	
Units: Percentage of participants				
number (confidence interval 95%)	37.5 (22.9 to 54.7)	45.8 (32.6 to 59.7)	46.4 (34.0 to 59.3)	

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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.

APD: 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 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: Percentage of participants				
number (confidence interval 95%)	20.0 (12.7 to 30.0)	38.7 (27.6 to 51.2)	24.3 (15.8 to 35.5)	31.0 (21.4 to 42.5)

End point values	NR: Bari 4 mg to 4 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	138			
Units: Percentage of participants				
number (confidence interval 95%)	22.5 (16.3 to 30.1)			

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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.

APD: 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: Percentage of participants				
number (confidence interval 95%)	31.6 (15.4 to 54.0)	36.8 (19.1 to 59.0)	31.4 (18.6 to 48.0)	

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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.

APD: 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: Percentage of participants				
number (confidence interval 95%)				
Week 4	57.8 (50.5 to 64.8)	67.0 (60.1 to 73.2)		
Week 16	56.7 (49.4 to 63.7)	62.9 (55.9 to 69.4)		
Week 24	55.6 (48.3 to 62.6)	57.2 (50.2 to 64.0)		
Week 52	50.6 (43.3 to 57.8)	46.9 (40.0 to 53.9)		

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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.

APD: Modified Intent-to-treat Population: All NR 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 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: Percentage of participants				
number (confidence interval 95%)				
Week 4	50.0 (34.1 to 65.9)	46.4 (29.5 to 64.2)		
Week 16	47.1 (31.5 to 63.3)	46.4 (29.5 to 64.2)		
Week 24	38.2 (23.9 to 55.0)	39.3 (23.6 to 57.6)		
Week 52	26.5 (14.6 to 43.1)	25.0 (12.7 to 43.4)		

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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.

APD: 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: Percentage of participants				
number (confidence interval 95%)				
Week 4	22.8 (17.3 to 29.4)	25.8 (20.1 to 32.4)		
Week 16	22.2 (16.8 to 28.8)	29.9 (23.9 to 36)		
Week 24	22.2 (16.8 to 28.8)	27.8 (22.0 to 34.5)		
Week 52	20.6 (15.3 to 27.0)	23.7 (18.3 to 30.2)		

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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.

APD: 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: Percentage of participants				
number (confidence interval 95%)				
Week 4	0 (0.0 to 10.2)	14.3 (5.7 to 31.5)		
Week 16	5.9 (1.6 to 19.1)	25.0 (12.7 to 43.4)		
Week 24	11.8 (4.7 to 26.6)	17.9 (7.9 to 35.6)		
Week 52	5.9 (1.6 to 19.1)	10.7 (3.7 to 27.2)		

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD: 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
Results were analyzed using NRI. Participants who either discontinued 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 EASI 75.

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: Percentage of participants				
number (confidence interval 95%)				
Week 4	38.9 (32.1 to 46.2)	46.9 (40.0 to 53.9)		
Week 16	43.9 (36.8 to 51.2)	53.6 (46.6 to 60.5)		

Week 24	45.0 (37.9 to 52.3)	45.4 (38.5 to 52.4)		
Week 52	41.1 (34.2 to 48.4)	38.7 (32.1 to 45.7)		

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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.
APD: Modified Intent-to-treat Population: All NR 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 NR population.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 24, 52
Results were analyzed using NRI. Participants who either discontinued 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 EASI 75.

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: Percentage of participants				
number (confidence interval 95%)				
Week 4	23.5 (12.4 to 40.0)	39.3 (23.6 to 57.6)		
Week 16	38.2 (23.9 to 55.0)	39.3 (23.6 to 57.6)		
Week 24	32.4 (19.1 to 49.2)	32.1 (17.9 to 50.7)		
Week 52	26.5 (14.6 to 43.1)	32.1 (17.9 to 50.7)		

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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.

APD: 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: Percentage of participants				
number (confidence interval 95%)	33.9 (27.2 to 41.5)	35.7 (28.9 to 43.1)		

Statistical analyses

No statistical analyses for this end point

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

End point title	NR: Percentage 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.

APD: 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: Percentage of participants				
number (confidence interval 95%)	20.6 (10.3 to 36.8)	26.9 (13.7 to 46.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved a Response of IGA 0, 1, or 2 Assessed at 16 Weeks After Rerandomization (Week 68) and Week 104 in Randomized Withdrawal and Downtitration Substudy (All Participants Entering the Substudy)

End point title	Percentage of Participants Who Achieved a Response of IGA 0, 1, or 2 Assessed at 16 Weeks After Rerandomization (Week 68) and Week 104 in Randomized Withdrawal and Downtitration Substudy (All Participants Entering the Substudy)

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. All missing values were imputed using modified last observation carried forward (mLOCF).

APD:Randomized Downtitration Withdrawal Substudy Population: All participants (including open-label participants) who are rerandomized at Week 52, entered the substudy, and received at least 1 dose of the IP in Period 2.

End point type	Secondary

End point timeframe:

Weeks 68, 104

End point values	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy	2 mg Bari to 2 mg Bari Substudy	4 mg Bari to Placebo Substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	91	92	84
Units: Percentage of participants				
number (confidence interval 95%)				
Week 68	44.6 (34.8 to 54.7)	70.3 (60.3 to 78.7)	92.4 (85.1 to 96.3)	50.0 (39.5 to 60.5)
Week 104	33.7 (24.9 to 43.8)	58.2 (48.0 to 67.8)	83.7 (74.8 to 89.9)	41.7 (31.7 to 52.3)

End point values	4 mg Bari to 2 mg Bari Substudy	4 mg Bari to 4 mg Bari Substudy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	84		
Units: Percentage of participants				
number (confidence interval 95%)				
Week 68	60.7 (50.0 to 70.5)	86.9 (78.1 to 92.5)		
Week 104	48.8 (38.4 to 59.3)	85.7 (76.7 to 91.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved a Response of IGA 0 or 1 Assessed at 16 Weeks After Rerandomization (Week 68) and Week 104 in Randomized Withdrawal and Downtitration substudy (All Participants Entering the Substudy)

End point title	Percentage of Participants Who Achieved a Response of IGA 0 or 1 Assessed at 16 Weeks After Rerandomization (Week 68) and Week 104 in Randomized Withdrawal and Downtitration substudy (All Participants Entering the Substudy)

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. All missing values were imputed using modified last observation carried forward (mLOCF).

APD: Randomized Downtitration Withdrawal Substudy Population: All participants (including open-label participants) who are rerandomized at Week 52, entered the substudy, and received at least 1 dose of the IP in Period 2.

End point type	Secondary

End point timeframe:

Weeks 68, 104

End point values	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy	2 mg Bari to 2 mg Bari Substudy	4 mg Bari to Placebo Substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	91	91	84
Units: Percentage of participants				
number (confidence interval 95%)				
Week 68	25.0 (17.3 to 34.7)	41.8 (32.2 to 52.0)	47.8 (37.9 to 57.9)	29.8 (21.0 to 40.2)
Week 104	21.7 (14.5 to 31.2)	38.5 (29.1 to 48.7)	42.4 (32.8 to 52.6)	33.3 (24.2 to 43.9)

End point values	4 mg Bari to 2 mg Bari Substudy	4 mg Bari to 4 mg Bari Substudy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	84		
Units: Percentage of participants				
number (confidence interval 95%)				
Week 68	45.2 (35.0 to 55.9)	51.2 (40.7 to 61.6)		
Week 104	35.7 (26.3 to 46.4)	47.6 (37.3 to 58.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Response of EASI75 From Baseline of Originating Study Assessed at 16 Weeks After Rerandomization (Week 68) and Week 104 in Randomized Withdrawal and Downtitration Substudy (All Participants Entering the Substudy)

End point title	Percentage of Participants Achieving Response of EASI75 From Baseline of Originating Study Assessed at 16 Weeks After Rerandomization (Week 68) and Week 104 in Randomized Withdrawal and Downtitration Substudy (All Participants Entering the Substudy)

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). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 to 72 (severe). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.
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 EASI 75.

End point type	Secondary

End point timeframe:

Weeks 68, 104
APD: Randomized Downtitration Withdrawal Substudy Population: All participants (including open-label participants) who are rerandomized at Week 52, entered the substudy, and received at least 1 dose of the IP in Period 2.

End point values	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy	2 mg Bari to 2 mg Bari Substudy	4 mg Bari to Placebo Substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	91	92	84
Units: Percentage of participants				
number (confidence interval 95%)				
Week 68	44.6 (34.8 to 54.7)	69.2 (59.1 to 77.8)	73.9 (64.1 to 81.8)	45.2 (35.0 to 55.9)
Week 104	43.5 (33.8 to 53.7)	58.2 (48.0 to 67.8)	72.8 (63.0 to 80.9)	41.7 (31.7 to 52.3)

End point values	4 mg Bari to 2 mg Bari Substudy	4 mg Bari to 4 mg Bari Substudy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	84		
Units: Percentage of participants				
number (confidence interval 95%)				
Week 68	58.3 (47.7 to 68.3)	79.8 (70.0 to 87.0)		
Week 104	58.3 (47.7 to 68.3)	73.8 (63.5 to 82.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Retreatment (Time to IGA ≥3) in Randomized Withdrawal and Down titration (All Participants Entering the Sub study)

End point title	Time to Retreatment (Time to IGA ≥3) in Randomized Withdrawal and Down titration (All Participants Entering the Sub study)

End point description:

Participants who entered the Substudy and relapsed with an IGA ≥3.

APD: Participants who received at least one dose of study medication during Week 52 to Week 200 in Study JAHN, entered the randomized down titration withdrawal sub study and experienced relapse (IGA ≥3) from Week 52 up to Week 200.

End point type	Secondary

End point timeframe:

Week 52 Up to Week 200

End point values	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy	2 mg Bari to 2 mg Bari Substudy	4 mg Bari to Placebo Substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	49	45	50
Units: Days				
median (inter-quartile range (Q1-Q3))	30.0 (28.0 to 87.0)	61.0 (29.0 to 269.0)	169.0 (56.0 to 368.0)	29.5 (26.0 to 113.0)

End point values	4 mg Bari to 2 mg Bari Substudy	4 mg Bari to 4 mg Bari Substudy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	39		
Units: Days				
median (inter-quartile range (Q1-Q3))	56.0 (29.0 to 170.0)	117.0 (57.0 to 289.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed at 16 Weeks After Rerandomization (Week 68) and Week 104 in Randomized Withdrawal and Downtitration substudy (Participants Entering the Substudy With IGA 0 or 1)

End point title	Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed at 16 Weeks After Rerandomization (Week 68) and Week 104 in Randomized Withdrawal and Downtitration substudy (Participants Entering the Substudy With 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. All missing values were imputed using modified last observation carried forward (mLOCF).
APD: Randomized Downtitration Withdrawal Substudy Population with Week 52 IGA of 0 or 1: All participants (including open-label participants) who are rerandomized at Week 52, entered the substudy with IGA 0 or 1, and received at least 1 dose of the IP in Period 2.

End point type	Secondary

End point timeframe:

Weeks 68, 104

End point values	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy	2 mg Bari to 2 mg Bari Substudy	4 mg Bari to Placebo Substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	48	43
Units: Percentage of participants				
number (confidence interval 95%)				
Week 68	55.1 (41.3 to 68.1)	89.6 (77.8 to 95.5)	95.8 (86.0 to 98.8)	72.1 (57.3 to 83.3)
Week 104	42.9 (30.0 to 56.7)	77.1 (63.5 to 86.7)	93.8 (83.2 to 97.9)	62.8 (47.9 to 75.6)

End point values	4 mg Bari to 2 mg Bari Substudy	4 mg Bari to 4 mg Bari Substudy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	43		
Units: Percentage of participants				
number (confidence interval 95%)				
Week 68	76.7 (62.3 to 86.8)	97.7 (87.9 to 99.6)		
Week 104	69.8 (54.9 to 81.4)	90.7 (78.4 to 96.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with a response of IGA 0 or 1 assessed at 16 weeks after rerandomization (Week 68) and Week 104 in Randomized Withdrawal and Downtitration Substudy (Participants Entering the Substudy with IGA 0 or 1)

End point title	Percentage of participants with a response of IGA 0 or 1 assessed at 16 weeks after rerandomization (Week 68) and Week 104 in Randomized Withdrawal and Downtitration Substudy (Participants Entering the Substudy with 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. All missing values were imputed using modified last observation carried forward (mLOCF).

APD: Randomized Downtitration Withdrawal Substudy Population with Week 52 IGA of 0 or 1: All participants (including open-label participants) who are rerandomized at Week 52, entered the substudy with IGA 0 or 1, and received at least 1 dose of the IP in Period 2.

End point type	Secondary

End point timeframe:

Weeks 68, 104

End point values	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy	2 mg Bari to 2 mg Bari Substudy	4 mg Bari to Placebo Substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	48	43
Units: Percentage of participants				
number (confidence interval 95%)				
Week 68	36.7 (24.7 to 50.7)	66.7 (52.5 to 78.3)	70.8 (56.8 to 81.8)	55.8 (41.1 to 69.6)
Week 104	32.7 (21.2 to 46.6)	60.4 (46.3 to 73.0)	60.4 (46.3 to 73.0)	58.1 (43.3 to 71.6)

End point values	4 mg Bari to 2 mg Bari Substudy	4 mg Bari to 4 mg Bari Substudy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	43		
Units: Percentage of participants				
number (confidence interval 95%)				
Week 68	69.8 (54.9 to 81.4)	74.4 (59.8 to 85.1)		
Week 104	55.8 (41.1 to 69.6)	62.8 (47.9 to 75.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with a response of EASI75 from baseline of originating study assessed at 16 weeks after rerandomization (Week 68) and Week 104 Randomized Withdrawal and Downtitration Substudy (Participants Entering the Substudy with IGA 0 or 1)

End point title	Percentage of participants with a response of EASI75 from baseline of originating study assessed at 16 weeks after rerandomization (Week 68) and Week 104 Randomized Withdrawal and Downtitration Substudy (Participants Entering the Substudy with IGA 0 or 1)

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). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD:Randomized Downtitration Withdrawal Substudy Population with Week 52 IGA of 0 or 1: All participants (including open-label participants) who are rerandomized at Week 52, entered the substudy with IGA 0 or 1, and received at least 1 dose of the IP in Period 2.

End point type	Secondary

End point timeframe:

Weeks 68, 104

End point values	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy	2 mg Bari to 2 mg Bari Substudy	4 mg Bari to Placebo Substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	48	43
Units: Percentage of participants				
number (confidence interval 95%)				
Week 68	63.3 (49.3 to 75.3)	89.6 (77.8 to 95.5)	83.3 (70.4 to 91.3)	72.1 (57.3 to 83.3)
Week 104	55.1 (41.3 to 68.1)	79.2 (65.7 to 88.3)	83.3 (70.4 to 91.3)	67.4 (52.5 to 79.5)

End point values	4 mg Bari to 2 mg Bari Substudy	4 mg Bari to 4 mg Bari Substudy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	43		
Units: Percentage of participants				
number (confidence interval 95%)				
Week 68	76.7 (62.3 to 86.8)	93 (81.4 to 97.6)		
Week 104	74.4 (59.8 to 85.1)	76.7 (62.3 to 86.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed Within 16 weeks of Retreatment (Week 68) Randomized Withdrawal and Downtitration (Participants Retreated During Substudy)

End point title	Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed Within 16 weeks of Retreatment (Week 68) Randomized Withdrawal and Downtitration (Participants Retreated During Substudy)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their 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. All missing values were imputed using modified last observation carried forward (mLOCF).

APD:Re-Treatment Substudy Population: A subset of Randomized Downtitration Withdrawal Substudy Population who experienced IGA ≥3 at any time in Period 2 and received at least 1 dose of retreatment of the original dose.

End point type	Secondary

End point timeframe:

Week 68

End point values	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy	2 mg Bari to 2 mg Bari Substudy	4 mg Bari to Placebo Substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	45	49	50
Units: Percentage of participants				
number (not applicable)	76.2	55.6	57.1	80.0

End point values	4 mg Bari to 2 mg Bari Substudy	4 mg Bari to 4 mg Bari Substudy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	39		
Units: Percentage of participants				
number (not applicable)	74.5	69.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with a response of IGA 0 or 1 Assessed Within 16 weeks of Retreatment (Week 68) Randomized Withdrawal and Downtitration (Participants Retreated During Substudy)

End point title	Percentage of participants with a response of IGA 0 or 1 Assessed Within 16 weeks of Retreatment (Week 68) Randomized Withdrawal and Downtitration (Participants Retreated During Substudy)

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. All missing values were imputed using modified last observation carried forward (mLOCF).

APD: Re-Treatment Substudy Population: A subset of Randomized Downtitration Withdrawal Substudy Population who experienced IGA ≥3 at any time in Period 2 and received at least 1 dose of retreatment of the original dose.

End point type	Secondary

End point timeframe:

Week 68

End point values	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy	2 mg Bari to 2 mg Bari Substudy	4 mg Bari to Placebo Substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	45	49	50
Units: Percentage of participants				
number (not applicable)	39.7	26.7	10.2	44.0

End point values	4 mg Bari to 2 mg Bari Substudy	4 mg Bari to 4 mg Bari Substudy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	39		
Units: Percentage of participants				
number (not applicable)	25.5	23.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Response of EASI75 from Baseline of Originating Study Assessed Within 16 Weeks of Retreatment (Week 68) Randomized Withdrawal and Downtitration (Participants Retreated During Substudy)

End point title	Percentage of Participants Achieving Response of EASI75 from Baseline of Originating Study Assessed Within 16 Weeks of Retreatment (Week 68) Randomized Withdrawal and Downtitration (Participants Retreated During Substudy)

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). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD: Re-Treatment Substudy Population: A subset of Randomized Downtitration Withdrawal Substudy Population who experienced IGA ≥3 at any time in Period 2 and received at least 1 dose of retreatment of the original dose.

End point type	Secondary

End point timeframe:

Week 68

End point values	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy	2 mg Bari to 2 mg Bari Substudy	4 mg Bari to Placebo Substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	45	49	50
Units: Percentage of participants				
number (not applicable)	71.4	44.4	55.1	70.0

End point values	4 mg Bari to 2 mg Bari Substudy	4 mg Bari to 4 mg Bari Substudy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	39		
Units: Percentage of participants				
number (not applicable)	53.2	61.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a response of IGA 0, 1, or 2 Assessed at Week 104 Participants Not Entered Into Substudy

End point title	Percentage of Participants with a response of IGA 0, 1, or 2 Assessed at Week 104 Participants Not Entered Into Substudy

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. All missing values were imputed using modified last observation carried forward (mLOCF).

APD: Period 2 Nonsubstudy Population: All participants randomized at Week 0 of main Study JAHN (excluding open-label participants) who were not eligible to enter the substudy at Week 52 and received at least 1 dose of the IP in Period 2

End point type	Secondary

End point timeframe:

Week 104

End point values	Placebo to Placebo Non-substudy	1 mg Bari to 1 mg Bari Non-substudy	2 mg Bari to 2 mg Bari Non-substudy	4 mg Bari to 4 mg Bari Non-substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	32	193	264
Units: Percentage of participants				
number (confidence interval 95%)	51.4 (40.0 to 62.8)	71.9 (54.6 to 84.4)	45.6 (38.7 to 52.6)	41.3 (35.5 to 47.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a response of IGA 0 or 1 Assessed at Week 104 Participants Not Entered Into Substudy

End point title	Percentage of Participants with a response of IGA 0 or 1 Assessed at Week 104 Participants Not Entered Into Substudy

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 score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All missing values were imputed using modified last observation carried forward (mLOCF).

APD: Period 2 Nonsubstudy Population: All participants randomized at Week 0 of main Study JAHN (excluding open-label participants) who were not eligible to enter the substudy at Week 52 and received at least 1 dose of the IP in Period 2

End point type	Secondary

End point timeframe:

Week 104

End point values	Placebo to Placebo Non-substudy	1 mg Bari to 1 mg Bari Non-substudy	2 mg Bari to 2 mg Bari Non-substudy	4 mg Bari to 4 mg Bari Non-substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	32	193	264
Units: Percentage of participants				
number (confidence interval 95%)	40.0 (29.3 to 51.7)	53.1 (36.4 to 69.1)	13.5 (9.4 to 19.0)	13.3 (9.7 to 17.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Response of EASI75 from Baseline of Originating Study Assessed at Week 104 Participants Not Entered Into Substudy

End point title	Percentage of Participants Achieving Response of EASI75 from Baseline of Originating Study Assessed at Week 104 Participants Not Entered Into Substudy

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). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD: Period 2 Nonsubstudy Population: All participants randomized at Week 0 of main Study JAHN (excluding open-label participants) who were not eligible to enter the substudy at Week 52 and received at least 1 dose of the IP in Period 2

End point type	Secondary

End point timeframe:

Week 104

End point values	Placebo to Placebo Non-substudy	1 mg Bari to 1 mg Bari Non-substudy	2 mg Bari to 2 mg Bari Non-substudy	4 mg Bari to 4 mg Bari Non-substudy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	32	193	264
Units: Percentage of participants				
number (confidence interval 95%)	54.3 (42.7 to 65.4)	65.6 (48.3 to 79.6)	40.9 (34.2 to 48.0)	39.8 (34.1 to 45.8)

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Baseline through Week 200

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	26.0

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-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	2 mg Bari to Placebo Substudy

Reporting group description:

Participants who received Baricitinib 2 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive placebo orally.

Reporting group title	2 mg Bari to 1 mg Bari Substudy

Reporting group description:

Participants who received Baricitinib 2 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive Baricitinib 1 mg orally.

Reporting group title	4 mg Bari to 4 mg Bari Non-substudy

Reporting group description:

Participants who received Baricitinib 4 mg at the start of Study JAHN who were not eligible to enter the substudy at week 52 assigned to this arm to receive Baricitinib 4 mg orally.

Reporting group title	4 mg Bari to Placebo Substudy

Reporting group description:

Participants who received Baricitinib 4 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive placebo orally.

Reporting group title	4 mg Bari to 2 mg Bari Substudy

Reporting group description:

Participants who received Baricitinib 4 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive Baricitinib 2 mg orally.

Reporting group title	4 mg Bari to 4 mg Bari Substudy

Reporting group description:

Participants who received Baricitinib 4 mg at the start of Study JAHN were rerandomized at week 52 or

assigned to this arm to receive Baricitinib 4 mg orally.

Reporting group title	Placebo to Placebo Non-substudy

Reporting group description:

Participants who received placebo at the start of Study JAHN who were not eligible to enter the substudy at week 52 assigned to this arm to receive placebo orally.

Reporting group title	1 mg Bari to 1 mg Bari Non-substudy

Reporting group description:

Participants who received Baricitinib 1 mg at the start of Study JAHN who were not eligible to enter the substudy at week 52 assigned to this arm to receive Baricitinib 1 mg orally.

Reporting group title	2 mg Bari to 2 mg Bari Non-substudy

Reporting group description:

Participants who received Baricitinib 2 mg at the start of Study JAHN who were not eligible to enter the substudy at week 52 assigned to this arm to receive Baricitinib 2 mg orally.

Reporting group title	2 mg Bari to 2 mg Bari Substudy

Reporting group description:

Participants who received Baricitinib 2 mg at the start of Study JAHN were rerandomized at week 52 or assigned to this arm to receive Baricitinib 2 mg orally.

Serious adverse events	Placebo	Bari 1-mg	Bari 2-mg
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 91 (5.49%)	1 / 45 (2.22%)	32 / 766 (4.18%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anaplastic large cell lymphoma t- and null-cell types			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
angiocentric lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
bladder neoplasm			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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

breast cancer stage ii			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
colon neoplasm			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
diffuse large b-cell lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
follicular lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
hodgkin's disease			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
peripheral t-cell lymphoma unspecified			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
prostate cancer			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed[1]	0 / 47 (0.00%)	0 / 29 (0.00%)	0 / 448 (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
rectal cancer			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
squamous cell carcinoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
testis cancer			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[2]	0 / 47 (0.00%)	0 / 29 (0.00%)	0 / 448 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[3]	0 / 44 (0.00%)	0 / 16 (0.00%)	0 / 318 (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
xanthogranuloma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
thrombophlebitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
vasculitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Surgical and medical procedures			
wisdom teeth removal			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Pregnancy, puerperium and perinatal conditions			
ectopic pregnancy			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[4]	0 / 44 (0.00%)	0 / 16 (0.00%)	0 / 318 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
death			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
Reproductive system and breast disorders			
uterine haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[5]	1 / 44 (2.27%)	0 / 16 (0.00%)	0 / 318 (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			
asthma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
epistaxis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
pulmonary embolism			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
pulmonary hypertension			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Product issues			
device dislocation			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Investigations			
eosinophil count increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
contusion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 91 (1.10%)	0 / 45 (0.00%)	0 / 766 (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
concussion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
facial bones fracture			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
fall			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
foot fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
meniscus injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
limb injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
ligament sprain			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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

multiple injuries			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
pneumocephalus			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
road traffic accident			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
skull fractured base			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
spinal fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
tibia fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Congenital, familial and genetic disorders			
thyroglossal cyst			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Cardiac disorders			
cardiovascular disorder			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
myocarditis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
myocardial infarction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
palpitations			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
sinus tachycardia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
ventricular extrasystoles			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Nervous system disorders			
brain stem haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
brain stem infarction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
dizziness			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
spinal cord haematoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Blood and lymphatic system disorders			
autoimmune haemolytic anaemia			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
hypochromic anaemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Ear and labyrinth disorders			
haematotympanum			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
tinnitus			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Eye disorders			
glaucoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
open angle glaucoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
retinopathy proliferative			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
retinal detachment			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
anal fistula			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
dental cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
intestinal obstruction			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
pancreatic failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
pancreatitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
drug-induced liver injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 91 (1.10%)	0 / 45 (0.00%)	0 / 766 (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 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
dermal cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
dermatitis atopic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 91 (1.10%)	0 / 45 (0.00%)	10 / 766 (1.31%)
occurrences causally related to treatment / all	0 / 1	0 / 0	3 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dermatitis exfoliative			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
parakeratosis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 91 (1.10%)	0 / 45 (0.00%)	0 / 766 (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 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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 and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
calculus urinary			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
nephrolithiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
renal colic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
renal failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
bursitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
compartment syndrome			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
intervertebral disc protrusion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
osteoarthritis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
osteonecrosis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess jaw			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
appendicitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	1 / 45 (2.22%)	0 / 766 (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
arthritis infective			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
bacteraemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
covid-19			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19 pneumonia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
cellulitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
diverticulitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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

endophthalmitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
eczema herpeticum			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	2 / 766 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
erysipeloid			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
hepatitis syphilitic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
influenza			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
osteomyelitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
otitis externa			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
pelvic abscess			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
postoperative wound infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 91 (1.10%)	0 / 45 (0.00%)	0 / 766 (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 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
pyelonephritis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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

sinusitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin bacterial infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
staphylococcal skin infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
superinfection bacterial			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
syphilis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
varicella			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (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
Metabolism and nutrition disorders			
dairy intolerance			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	1 / 766 (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

Serious adverse events	Bari 4-mg	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy
Total subjects affected by serious adverse events			
subjects affected / exposed	40 / 743 (5.38%)	2 / 92 (2.17%)	1 / 91 (1.10%)
number of deaths (all causes)	1	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anaplastic large cell lymphoma t- and null-cell types			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angiocentric lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
bladder neoplasm			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
breast cancer stage ii			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
colon neoplasm			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
diffuse large b-cell lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
follicular lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
hodgkin's disease			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
peripheral t-cell lymphoma unspecified			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
prostate cancer			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed[1]	0 / 504 (0.00%)	0 / 48 (0.00%)	0 / 61 (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
rectal cancer			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
squamous cell carcinoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
testis cancer			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[2]	0 / 504 (0.00%)	0 / 48 (0.00%)	0 / 61 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[3]	0 / 239 (0.00%)	0 / 44 (0.00%)	0 / 30 (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
xanthogranuloma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
thrombophlebitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 743 (0.27%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vasculitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
wisdom teeth removal			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
Pregnancy, puerperium and perinatal conditions			
ectopic pregnancy			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[4]	0 / 239 (0.00%)	0 / 44 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
death			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	1 / 92 (1.09%)	0 / 91 (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 26.0			
subjects affected / exposed[5]	0 / 239 (0.00%)	0 / 44 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
epistaxis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
pulmonary embolism			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary hypertension			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
Product issues			
device dislocation			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
Investigations			
eosinophil count increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
contusion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
concussion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
facial bones fracture			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
fall			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
foot fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
meniscus injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
limb injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
ligament sprain			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
joint dislocation			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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

multiple injuries			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
pneumocephalus			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
skull fractured base			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
tibia fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
Congenital, familial and genetic disorders			
thyroglossal cyst			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
Cardiac disorders			
cardiovascular disorder			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
myocarditis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
myocardial infarction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
palpitations			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
sinus tachycardia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular extrasystoles			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
brain stem haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
brain stem infarction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
dizziness			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
spinal cord haematoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
autoimmune haemolytic anaemia			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
hypochromic anaemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
Ear and labyrinth disorders			
haematotympanum			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tinnitus			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
Eye disorders			
glaucoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
open angle glaucoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
retinopathy proliferative			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
retinal detachment			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
anal fistula			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dental cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
intestinal obstruction			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
pancreatic failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
pancreatitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
drug-induced liver injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
hepatic failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	1 / 92 (1.09%)	0 / 91 (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
dermal cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
dermatitis atopic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	9 / 743 (1.21%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	5 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dermatitis exfoliative			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
parakeratosis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
urticaria			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
calculus urinary			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
nephrolithiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
renal colic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
renal failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
bursitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
compartment syndrome			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
intervertebral disc protrusion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
osteoarthritis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
osteonecrosis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
Infections and infestations			
abscess jaw			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
appendicitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
bacteraemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19 pneumonia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 743 (0.27%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

endophthalmitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
eczema herpeticum			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	6 / 743 (0.81%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	5 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipeloid			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
hepatitis syphilitic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
influenza			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
osteomyelitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
otitis externa			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
pelvic abscess			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
postoperative wound infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
psoas abscess			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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

sinusitis alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
skin bacterial infection alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal bacteraemia alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal skin infection alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
superinfection bacterial alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 743 (0.27%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syphilis alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 743 (0.13%)	0 / 92 (0.00%)	0 / 91 (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
varicella alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (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
Metabolism and nutrition disorders			
dairy intolerance			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	4 mg Bari to 4 mg Bari Non-substudy	4 mg Bari to Placebo Substudy	4 mg Bari to 2 mg Bari Substudy
Total subjects affected by serious adverse events			
subjects affected / exposed	25 / 264 (9.47%)	3 / 84 (3.57%)	1 / 84 (1.19%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anaplastic large cell lymphoma t- and null-cell types			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
angiocentric lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	1 / 84 (1.19%)	0 / 84 (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
bladder neoplasm			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
breast cancer stage ii			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
colon neoplasm			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
diffuse large b-cell lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
follicular lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
hodgkin's disease			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
peripheral t-cell lymphoma unspecified			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (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
prostate cancer			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed[1]	0 / 190 (0.00%)	0 / 48 (0.00%)	0 / 54 (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
rectal cancer			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
squamous cell carcinoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
testis cancer			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[2]	0 / 190 (0.00%)	0 / 48 (0.00%)	0 / 54 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[3]	1 / 74 (1.35%)	0 / 36 (0.00%)	0 / 30 (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
xanthogranuloma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
thrombophlebitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
vasculitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Surgical and medical procedures			
wisdom teeth removal			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Pregnancy, puerperium and perinatal conditions			
ectopic pregnancy			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[4]	0 / 74 (0.00%)	0 / 36 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (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
death			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Reproductive system and breast disorders			
uterine haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[5]	0 / 74 (0.00%)	0 / 36 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
epistaxis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
pulmonary embolism			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary hypertension			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Product issues			
device dislocation			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 264 (0.76%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
eosinophil count increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
contusion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
concussion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	1 / 84 (1.19%)	0 / 84 (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
facial bones fracture			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
fall			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
foot fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
meniscus injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
limb injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
ligament sprain			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
joint dislocation			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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

multiple injuries			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
pneumocephalus			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
road traffic accident			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
skull fractured base			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
spinal fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
tibia fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Congenital, familial and genetic disorders			
thyroglossal cyst			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (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
Cardiac disorders			
cardiovascular disorder			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
myocarditis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
myocardial infarction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
palpitations			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (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
sinus tachycardia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
ventricular extrasystoles			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Nervous system disorders			
brain stem haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (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
brain stem infarction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	1 / 84 (1.19%)	0 / 84 (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
dizziness			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
spinal cord haematoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Blood and lymphatic system disorders			
autoimmune haemolytic anaemia			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
hypochromic anaemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Ear and labyrinth disorders			
haematotympanum			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
tinnitus			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Eye disorders			
glaucoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
open angle glaucoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
retinopathy proliferative			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
retinal detachment			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 264 (0.76%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
anal fistula			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (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
colitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
dental cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
intestinal obstruction			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
pancreatic failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
pancreatitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
drug-induced liver injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
hepatic failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
dermal cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
dermatitis atopic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	5 / 264 (1.89%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	1 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dermatitis exfoliative			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
parakeratosis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
urticaria			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
calculus urinary			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
nephrolithiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
renal colic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
renal failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
bursitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
compartment syndrome			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
intervertebral disc protrusion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (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
osteoarthritis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (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
osteonecrosis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess jaw			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
appendicitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
bacteraemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19 pneumonia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	4 / 264 (1.52%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	4 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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

endophthalmitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
eczema herpeticum			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
erysipeloid			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatitis syphilitic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
influenza			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
osteomyelitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
otitis externa			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
pelvic abscess			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
postoperative wound infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
psoas abscess			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
pyelonephritis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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

sinusitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin bacterial infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
staphylococcal skin infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
superinfection bacterial			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
syphilis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
varicella			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (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
Metabolism and nutrition disorders			
dairy intolerance			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	4 mg Bari to 4 mg Bari Substudy	Placebo to Placebo Non-substudy	1 mg Bari to 1 mg Bari Non-substudy
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 84 (13.10%)	1 / 70 (1.43%)	3 / 32 (9.38%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anaplastic large cell lymphoma t- and null-cell types			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
angiocentric lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
bladder neoplasm			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
breast cancer stage ii			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	1 / 84 (1.19%)	0 / 70 (0.00%)	0 / 32 (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
colon neoplasm			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 84 (1.19%)	0 / 70 (0.00%)	0 / 32 (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
diffuse large b-cell lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
follicular lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
hodgkin's disease			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 84 (1.19%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral t-cell lymphoma unspecified			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
prostate cancer			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed[1]	0 / 53 (0.00%)	0 / 36 (0.00%)	0 / 20 (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
rectal cancer			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
squamous cell carcinoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
testis cancer			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[2]	0 / 53 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[3]	0 / 31 (0.00%)	0 / 34 (0.00%)	0 / 12 (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
xanthogranuloma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 84 (1.19%)	0 / 70 (0.00%)	0 / 32 (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
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	1 / 84 (1.19%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombophlebitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
vasculitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Surgical and medical procedures			
wisdom teeth removal			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Pregnancy, puerperium and perinatal conditions			
ectopic pregnancy			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[4]	0 / 31 (0.00%)	0 / 34 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
death			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Reproductive system and breast disorders			
uterine haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[5]	0 / 31 (0.00%)	0 / 34 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
epistaxis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
pulmonary embolism			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 84 (1.19%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary hypertension			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	1 / 84 (1.19%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Investigations			
eosinophil count increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
contusion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
concussion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
facial bones fracture			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
fall			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
foot fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
meniscus injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
limb injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
ligament sprain			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
joint dislocation			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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

multiple injuries			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
pneumocephalus			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
road traffic accident			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
skull fractured base			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
spinal fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
tibia fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Congenital, familial and genetic disorders			
thyroglossal cyst			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Cardiac disorders			
cardiovascular disorder			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	1 / 70 (1.43%)	0 / 32 (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
myocarditis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
myocardial infarction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 84 (1.19%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
palpitations			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
sinus tachycardia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
ventricular extrasystoles			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Nervous system disorders			
brain stem haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
brain stem infarction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
dizziness			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
spinal cord haematoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Blood and lymphatic system disorders			
autoimmune haemolytic anaemia			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypochromic anaemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Ear and labyrinth disorders			
haematotympanum			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
tinnitus			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Eye disorders			
glaucoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
open angle glaucoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
retinopathy proliferative			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
retinal detachment			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 84 (1.19%)	0 / 70 (0.00%)	0 / 32 (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
Gastrointestinal disorders			
anal fistula			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
dental cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
intestinal obstruction			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
pancreatic failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
pancreatitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
drug-induced liver injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
hepatic failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
dermal cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
dermatitis atopic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
dermatitis exfoliative			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
parakeratosis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
urticaria			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
calculus urinary			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
nephrolithiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
renal colic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
renal failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 84 (2.38%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
compartment syndrome			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
intervertebral disc protrusion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	1 / 70 (1.43%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
osteonecrosis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess jaw			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
appendicitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
bacteraemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19 pneumonia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
cellulitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
diverticulitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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

endophthalmitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
eczema herpeticum			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
erysipeloid			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
hepatitis syphilitic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 84 (1.19%)	0 / 70 (0.00%)	0 / 32 (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
influenza			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
osteomyelitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
otitis externa			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pelvic abscess			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 84 (1.19%)	0 / 70 (0.00%)	0 / 32 (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 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
postoperative wound infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
psoas abscess			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
pyelonephritis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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

sinusitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin bacterial infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
staphylococcal skin infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
superinfection bacterial			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
syphilis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
varicella			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (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
Metabolism and nutrition disorders			
dairy intolerance			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	2 mg Bari to 2 mg Bari Non-substudy	2 mg Bari to 2 mg Bari Substudy	
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 249 (6.43%)	3 / 92 (3.26%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anaplastic large cell lymphoma t- and null-cell types			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
angiocentric lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder neoplasm			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
breast cancer stage ii			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon neoplasm			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diffuse large b-cell lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
follicular lymphoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hodgkin's disease			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral t-cell lymphoma unspecified			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostate cancer			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed[1]	1 / 159 (0.63%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal cancer			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
squamous cell carcinoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
testis cancer			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[2]	0 / 159 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
uterine leiomyoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[3]	0 / 90 (0.00%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
xanthogranuloma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
thrombophlebitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vasculitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
wisdom teeth removal			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
ectopic pregnancy			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[4]	1 / 90 (1.11%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
death			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
uterine haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[5]	0 / 90 (0.00%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 249 (0.80%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
epistaxis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary embolism			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary hypertension			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
device dislocation			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
eosinophil count increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
contusion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
concussion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
facial bones fracture			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
fall			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
foot fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
meniscus injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
limb injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ligament sprain			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
joint dislocation			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

multiple injuries			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumocephalus			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
road traffic accident			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
skull fractured base			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tibia fracture			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
thyroglossal cyst			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
cardiovascular disorder			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myocarditis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myocardial infarction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
palpitations			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sinus tachycardia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ventricular extrasystoles			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
brain stem haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
brain stem infarction			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dizziness			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal cord haematoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
autoimmune haemolytic anaemia			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypochromic anaemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
haematotympanum			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tinnitus			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
glaucoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
open angle glaucoma			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
retinopathy proliferative			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
retinal detachment			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
anal fistula			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
colitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dental cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal obstruction			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatic failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
drug-induced liver injury			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dermal cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dermatitis atopic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 249 (0.80%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dermatitis exfoliative			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
parakeratosis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
urticaria			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
calculus urinary			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
nephrolithiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	1 / 92 (1.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal colic			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal failure			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bursitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
compartment syndrome			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc protrusion			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteoarthritis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteonecrosis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
abscess jaw			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
appendicitis			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	1 / 92 (1.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
arthritis infective			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bacteraemia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
covid-19			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 249 (0.40%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
covid-19 pneumonia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diverticulitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

endophthalmitis				
alternative dictionary used: MedDRA 26.0				
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
eczema herpeticum				
alternative dictionary used: MedDRA 26.0				
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
erysipelas				
alternative dictionary used: MedDRA 26.0				
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
erysipeloid				
alternative dictionary used: MedDRA 26.0				
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
hepatitis syphilitic				
alternative dictionary used: MedDRA 26.0				
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
influenza				
alternative dictionary used: MedDRA 26.0				
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
osteomyelitis				
alternative dictionary used: MedDRA 26.0				

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
otitis externa			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pelvic abscess			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
postoperative wound infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
psoas abscess			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyelonephritis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

sinusitis				
alternative dictionary used: MedDRA 26.0				
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
skin bacterial infection				
alternative dictionary used: MedDRA 26.0				
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
staphylococcal bacteraemia				
alternative dictionary used: MedDRA 26.0				
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
staphylococcal skin infection				
alternative dictionary used: MedDRA 26.0				
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
superinfection bacterial				
alternative dictionary used: MedDRA 26.0				
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
syphilis				
alternative dictionary used: MedDRA 26.0				
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
varicella				
alternative dictionary used: MedDRA 26.0				

subjects affected / exposed	0 / 249 (0.00%)	1 / 92 (1.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
dairy intolerance			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	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: Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.
[2] - 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.
[3] - 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.
[4] - 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.
[5] - 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: Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

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

Non-serious adverse events	Placebo	Bari 1-mg	Bari 2-mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 91 (23.08%)	14 / 45 (31.11%)	263 / 766 (34.33%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	13 / 766 (1.70%)
occurrences (all)	0	0	13
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	1 / 45 (2.22%)	12 / 766 (1.57%)
occurrences (all)	0	1	13
hepatic enzyme increased			

alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 91 (1.10%)	0 / 45 (0.00%)	2 / 766 (0.26%)
occurrences (all)	1	0	2
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	6 / 91 (6.59%)	1 / 45 (2.22%)	46 / 766 (6.01%)
occurrences (all)	7	1	58
General disorders and administration site conditions			
pyrexia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	2 / 45 (4.44%)	17 / 766 (2.22%)
occurrences (all)	0	2	18
Skin and subcutaneous tissue disorders			
dermal cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 91 (1.10%)	0 / 45 (0.00%)	7 / 766 (0.91%)
occurrences (all)	1	0	8
Infections and infestations			
covid-19			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	0 / 45 (0.00%)	0 / 766 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	1 / 91 (1.10%)	0 / 45 (0.00%)	19 / 766 (2.48%)
occurrences (all)	2	0	21
herpes zoster			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 91 (2.20%)	0 / 45 (0.00%)	13 / 766 (1.70%)
occurrences (all)	2	0	13

oral herpes			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 91 (2.20%)	0 / 45 (0.00%)	34 / 766 (4.44%)
occurrences (all)	3	0	47
nasopharyngitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	10 / 91 (10.99%)	9 / 45 (20.00%)	106 / 766 (13.84%)
occurrences (all)	12	15	140
urinary tract infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 91 (0.00%)	1 / 45 (2.22%)	20 / 766 (2.61%)
occurrences (all)	0	2	22
upper respiratory tract infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	3 / 91 (3.30%)	0 / 45 (0.00%)	43 / 766 (5.61%)
occurrences (all)	3	0	65
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[6]	0 / 44 (0.00%)	0 / 16 (0.00%)	4 / 318 (1.26%)
occurrences (all)	0	0	6

Non-serious adverse events	Bari 4-mg	2 mg Bari to Placebo Substudy	2 mg Bari to 1 mg Bari Substudy
Total subjects affected by non-serious adverse events			
subjects affected / exposed	268 / 743 (36.07%)	15 / 92 (16.30%)	27 / 91 (29.67%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	10 / 743 (1.35%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences (all)	10	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	18 / 743 (2.42%)	1 / 92 (1.09%)	1 / 91 (1.10%)
occurrences (all)	18	1	1
hepatic enzyme increased			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	2 / 743 (0.27%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	22 / 743 (2.96%)	3 / 92 (3.26%)	4 / 91 (4.40%)
occurrences (all)	37	3	4
General disorders and administration site conditions			
pyrexia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	19 / 743 (2.56%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences (all)	20	0	0
Skin and subcutaneous tissue disorders			
dermal cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	4 / 743 (0.54%)	0 / 92 (0.00%)	0 / 91 (0.00%)
occurrences (all)	4	0	0
urticaria			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	14 / 743 (1.88%)	0 / 92 (0.00%)	1 / 91 (1.10%)
occurrences (all)	19	0	1
Infections and infestations			
covid-19			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 743 (0.00%)	2 / 92 (2.17%)	9 / 91 (9.89%)
occurrences (all)	0	2	9
folliculitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	12 / 743 (1.62%)	0 / 92 (0.00%)	5 / 91 (5.49%)
occurrences (all)	13	0	5
herpes zoster			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	21 / 743 (2.83%)	0 / 92 (0.00%)	1 / 91 (1.10%)
occurrences (all)	23	0	1
oral herpes			

alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	40 / 743 (5.38%)	1 / 92 (1.09%)	0 / 91 (0.00%)
occurrences (all)	51	2	0
nasopharyngitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	122 / 743 (16.42%)	5 / 92 (5.43%)	3 / 91 (3.30%)
occurrences (all)	173	6	3
urinary tract infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	7 / 743 (0.94%)	1 / 92 (1.09%)	2 / 91 (2.20%)
occurrences (all)	8	1	2
upper respiratory tract infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	44 / 743 (5.92%)	4 / 92 (4.35%)	3 / 91 (3.30%)
occurrences (all)	56	4	5
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[6]	0 / 239 (0.00%)	0 / 44 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	0	3

Non-serious adverse events	4 mg Bari to 4 mg Bari Non-substudy	4 mg Bari to Placebo Substudy	4 mg Bari to 2 mg Bari Substudy
Total subjects affected by non-serious adverse events			
subjects affected / exposed	110 / 264 (41.67%)	16 / 84 (19.05%)	21 / 84 (25.00%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	6 / 264 (2.27%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences (all)	6	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	6 / 264 (2.27%)	0 / 84 (0.00%)	1 / 84 (1.19%)
occurrences (all)	6	0	1
hepatic enzyme increased			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	1 / 264 (0.38%)	0 / 84 (0.00%)	1 / 84 (1.19%)
occurrences (all)	1	0	1
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	10 / 264 (3.79%)	1 / 84 (1.19%)	1 / 84 (1.19%)
occurrences (all)	11	4	1
General disorders and administration site conditions			
pyrexia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	4 / 264 (1.52%)	0 / 84 (0.00%)	1 / 84 (1.19%)
occurrences (all)	7	0	1
Skin and subcutaneous tissue disorders			
dermal cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 264 (0.00%)	0 / 84 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 264 (0.76%)	1 / 84 (1.19%)	1 / 84 (1.19%)
occurrences (all)	2	1	1
Infections and infestations			
covid-19			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	29 / 264 (10.98%)	7 / 84 (8.33%)	4 / 84 (4.76%)
occurrences (all)	31	8	5
folliculitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	6 / 264 (2.27%)	1 / 84 (1.19%)	0 / 84 (0.00%)
occurrences (all)	6	1	0
herpes zoster			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	26 / 264 (9.85%)	0 / 84 (0.00%)	2 / 84 (2.38%)
occurrences (all)	27	0	2
oral herpes			

alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	8 / 264 (3.03%)	1 / 84 (1.19%)	4 / 84 (4.76%)
occurrences (all)	9	7	5
nasopharyngitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	26 / 264 (9.85%)	6 / 84 (7.14%)	8 / 84 (9.52%)
occurrences (all)	32	12	9
urinary tract infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	5 / 264 (1.89%)	3 / 84 (3.57%)	6 / 84 (7.14%)
occurrences (all)	9	3	7
upper respiratory tract infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	10 / 264 (3.79%)	0 / 84 (0.00%)	2 / 84 (2.38%)
occurrences (all)	18	0	2
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[6]	0 / 74 (0.00%)	0 / 36 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	4 mg Bari to 4 mg Bari Substudy	Placebo to Placebo Non-substudy	1 mg Bari to 1 mg Bari Non-substudy
Total subjects affected by non-serious adverse events			
subjects affected / exposed	42 / 84 (50.00%)	14 / 70 (20.00%)	14 / 32 (43.75%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 84 (2.38%)	1 / 70 (1.43%)	3 / 32 (9.38%)
occurrences (all)	2	1	3
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	5 / 84 (5.95%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences (all)	6	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	2 / 84 (2.38%)	0 / 70 (0.00%)	2 / 32 (6.25%)
occurrences (all)	2	0	2
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 84 (2.38%)	3 / 70 (4.29%)	0 / 32 (0.00%)
occurrences (all)	2	5	0
General disorders and administration site conditions			
pyrexia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 84 (2.38%)	2 / 70 (2.86%)	2 / 32 (6.25%)
occurrences (all)	2	2	2
Skin and subcutaneous tissue disorders			
dermal cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 84 (2.38%)	0 / 70 (0.00%)	2 / 32 (6.25%)
occurrences (all)	3	0	2
urticaria			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	0 / 84 (0.00%)	4 / 70 (5.71%)	1 / 32 (3.13%)
occurrences (all)	0	4	1
Infections and infestations			
covid-19			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	14 / 84 (16.67%)	3 / 70 (4.29%)	7 / 32 (21.88%)
occurrences (all)	15	4	7
folliculitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	4 / 84 (4.76%)	1 / 70 (1.43%)	0 / 32 (0.00%)
occurrences (all)	4	1	0
herpes zoster			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 84 (2.38%)	0 / 70 (0.00%)	0 / 32 (0.00%)
occurrences (all)	2	0	0
oral herpes			

alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	2 / 84 (2.38%)	2 / 70 (2.86%)	0 / 32 (0.00%)
occurrences (all)	2	3	0
nasopharyngitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	11 / 84 (13.10%)	1 / 70 (1.43%)	1 / 32 (3.13%)
occurrences (all)	14	1	1
urinary tract infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	5 / 84 (5.95%)	1 / 70 (1.43%)	0 / 32 (0.00%)
occurrences (all)	8	1	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	5 / 84 (5.95%)	1 / 70 (1.43%)	1 / 32 (3.13%)
occurrences (all)	7	2	1
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[6]	1 / 31 (3.23%)	0 / 34 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	2 mg Bari to 2 mg Bari Non-substudy	2 mg Bari to 2 mg Bari Substudy	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	96 / 249 (38.55%)	38 / 92 (41.30%)	
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	4 / 249 (1.61%)	1 / 92 (1.09%)	
occurrences (all)	4	1	
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	5 / 249 (2.01%)	4 / 92 (4.35%)	
occurrences (all)	5	5	
hepatic enzyme increased			
alternative dictionary used: MedDRA 26.0			

subjects affected / exposed	0 / 249 (0.00%)	0 / 92 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	14 / 249 (5.62%)	5 / 92 (5.43%)	
occurrences (all)	15	6	
General disorders and administration site conditions			
pyrexia			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	7 / 249 (2.81%)	1 / 92 (1.09%)	
occurrences (all)	7	1	
Skin and subcutaneous tissue disorders			
dermal cyst			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	3 / 249 (1.20%)	1 / 92 (1.09%)	
occurrences (all)	3	1	
urticaria			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	4 / 249 (1.61%)	1 / 92 (1.09%)	
occurrences (all)	5	1	
Infections and infestations			
covid-19			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	33 / 249 (13.25%)	14 / 92 (15.22%)	
occurrences (all)	33	15	
folliculitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	10 / 249 (4.02%)	2 / 92 (2.17%)	
occurrences (all)	10	2	
herpes zoster			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	13 / 249 (5.22%)	4 / 92 (4.35%)	
occurrences (all)	16	4	
oral herpes			

alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	9 / 249 (3.61%)	4 / 92 (4.35%)	
occurrences (all)	14	4	
nasopharyngitis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	27 / 249 (10.84%)	10 / 92 (10.87%)	
occurrences (all)	30	14	
urinary tract infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	3 / 249 (1.20%)	2 / 92 (2.17%)	
occurrences (all)	3	3	
upper respiratory tract infection			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed	11 / 249 (4.42%)	3 / 92 (3.26%)	
occurrences (all)	16	5	
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 26.0			
subjects affected / exposed[6]	0 / 90 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	

Notes:

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events only occurring in male or female participants have had the number of participants At Risk adjusted accordingly.

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