Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 3 Study of Baricitinib in Patients with Systemic Lupus Erythematosus

Summary

EudraCT number	2017-005026-37
Trial protocol	GB AT BE HU CZ GR NL HR
Global end of trial date	09 March 2022

Results information

Result version number	v2 (current)
This version publication date	25 February 2023
First version publication date	27 October 2022
Version creation reason	• Correction of full data set Revisions

Trial information

Trial identification

Sponsor protocol code	I4V-MC-JAHZ

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03616912
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16676

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	09 March 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 March 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The reason for this study is to see how effective and safe the study drug known as baricitinib is in participants with systemic lupus erythematosus (SLE).

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: -

Evidence for comparator: -

Actual start date of recruitment	02 August 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	Australia: 31
Country: Number of subjects enrolled	Austria: 3
Country: Number of subjects enrolled	Belgium: 4
Country: Number of subjects enrolled	Brazil: 83
Country: Number of subjects enrolled	China: 116
Country: Number of subjects enrolled	Croatia: 10
Country: Number of subjects enrolled	Czechia: 38
Country: Number of subjects enrolled	Germany: 45
Country: Number of subjects enrolled	Greece: 18
Country: Number of subjects enrolled	Hungary: 50
Country: Number of subjects enrolled	Israel: 8
Country: Number of subjects enrolled	Mexico: 136
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	Russian Federation: 71
Country: Number of subjects enrolled	Switzerland: 8
Country: Number of subjects enrolled	Taiwan: 39
Country: Number of subjects enrolled	United Kingdom: 13
Country: Number of subjects enrolled	United States: 146
Worldwide total number of subjects	821
EEA total number of subjects	170

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)	1
Adults (18-64 years)	789
From 65 to 84 years	31
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

As only year of birth was collected on case report form, for one participant, age at enrollment was calculated as 17 years old, using the imputed day and month of "01Jul ". Therefore, not necessarily indicating the participant's actual age.

Pre-assignment

Screening details:

One investigational site with seven participants was excluded from analysis due to confirmed misconduct.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received two placebo tablets: one matching 4 mg Baricitinib and one matching 2 mg Baricitinib administered orally every day (QD) for 52 weeks.

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:

Participants received two placebo tablets: one matching 4 mg Baricitinib and one matching 2 mg Baricitinib administered orally QD for 52 weeks.

Arm title	2 mg Baricitinib

Arm description:

Participants received one 2 mg Baricitinib tablet and one placebo tablet matching 4 mg Baricitinib administered orally QD for 52 weeks.

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:

Participants received one 2 mg Baricitinib tablet and one placebo tablet matching 4 mg Baricitinib administered orally QD for 52 weeks.

Arm title	4 mg Baricitinib

Arm description:

Participants received one 4 mg Baricitinib tablet and one placebo tablet matching 2 mg Baricitinib administered orally every day (QD) for 52 weeks.

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:

Participants received one 4 mg Baricitinib tablet and one placebo tablet matching 2 mg Baricitinib administered orally every day (QD) for 52 weeks.

Arm title	Placebo Maximum Extended Enrollment (MEE)

Arm description:

Participants received two placebo tablets: one matching 4 mg Baricitinib and one matching 2 mg Baricitinib administered orally QD for 52 weeks.

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:

Participants received two placebo tablets: one matching 4 mg Baricitinib and one matching 2 mg Baricitinib administered orally QD for 52 weeks.

Arm title	2 mg Baricitinib (MEE)

Arm description:

Participants received one 2 mg Baricitinib tablet and 1 placebo tablet matching 4 mg Baricitinib administered QD for 52 weeks.

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:

Participants received one 2 mg Baricitinib tablet and 1 placebo tablet matching 4 mg Baricitinib administered QD for 52 weeks.

Arm title	4 mg Baricitinib (MEE)

Arm description:

Participants received one 4 mg Baricitinib tablet and one placebo tablet matching 2 mg Baricitinib administered orally QD for 52 weeks.

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:

Participants received one 4 mg Baricitinib tablet and one placebo tablet matching 2 mg Baricitinib administered orally QD for 52 weeks.

Number of subjects in period 1	Placebo	2 mg Baricitinib	4 mg Baricitinib
Started	253	255	252
Received at Least One Dose of Study Drug	253	255	252
Completed	200	210	206
Not completed	53	45	46
Adverse event, serious fatal	1	1	-
Consent withdrawn by subject	12	12	15
Physician decision	2	-	-
Adverse event, non-fatal	17	21	9
Due to Epidemic/Pandemic	4	2	5
Protocol Deviation	1	1	-
Pregnancy	1	-	4
Protocol Violation	1	-	2
Study Terminated by Sponsor	-	-	-
Lost to follow-up	1	2	3
Lack of efficacy	13	6	8

Number of subjects in period 1	Placebo Maximum Extended Enrollment (MEE)	2 mg Baricitinib (MEE)	4 mg Baricitinib (MEE)
Started	21	20	20
Received at Least One Dose of Study Drug	21	20	20
Completed	5	5	6
Not completed	16	15	14
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	2	-	2
Physician decision	-	1	-
Adverse event, non-fatal	-	-	-
Due to Epidemic/Pandemic	-	-	-
Protocol Deviation	-	-	-
Pregnancy	-	-	-
Protocol Violation	-	-	-
Study Terminated by Sponsor	10	9	11
Lost to follow-up	-	-	-
Lack of efficacy	4	5	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received two placebo tablets: one matching 4 mg Baricitinib and one matching 2 mg Baricitinib administered orally every day (QD) for 52 weeks.	
Reporting group title	2 mg Baricitinib
Reporting group description:	
Participants received one 2 mg Baricitinib tablet and one placebo tablet matching 4 mg Baricitinib administered orally QD for 52 weeks.	
Reporting group title	4 mg Baricitinib
Reporting group description:	
Participants received one 4 mg Baricitinib tablet and one placebo tablet matching 2 mg Baricitinib administered orally every day (QD) for 52 weeks.	
Reporting group title	Placebo Maximum Extended Enrollment (MEE)
Reporting group description:	
Participants received two placebo tablets: one matching 4 mg Baricitinib and one matching 2 mg Baricitinib administered orally QD for 52 weeks.	
Reporting group title	2 mg Baricitinib (MEE)
Reporting group description:	
Participants received one 2 mg Baricitinib tablet and 1 placebo tablet matching 4 mg Baricitinib administered QD for 52 weeks.	
Reporting group title	4 mg Baricitinib (MEE)
Reporting group description:	
Participants received one 4 mg Baricitinib tablet and one placebo tablet matching 2 mg Baricitinib administered orally QD for 52 weeks.	

Reporting group values	Placebo	2 mg Baricitinib	4 mg Baricitinib
Number of subjects	253	255	252
Age categorical Units: Subjects			
Age continuous			
Analysis Population Description (APD): All randomized participants who received at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: years			
arithmetic mean	42.00	42.90	41.50
standard deviation	± 11.98	± 12.44	± 12.88
Gender categorical			
APD: All randomized participants who receive at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: Subjects			
Female	237	238	237
Male	16	17	15
Ethnicity (NIH/OMB)			
APD: All randomized participants who receive at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: Subjects			

Hispanic or Latino	4	13	11
Not Hispanic or Latino	42	35	38
Unknown or Not Reported	207	207	203
Race (NIH/OMB)			
APD: All randomized participants who receive at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: Subjects			
American Indian or Alaska Native	12	15	7
Asian	33	39	34
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	36	23	30
White	168	172	177
More than one race	1	2	0
Unknown or Not Reported	3	4	4
Region of Enrollment			
APD: All randomized participants who receive at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: Subjects			
Australia	10	9	12
Austria	0	1	2
Belgium	2	1	1
Brazil	38	22	23
China	16	21	18
Croatia	5	3	2
Czechia	18	11	9
Germany	14	14	17
Greece	4	9	5
Hungary	13	18	19
Israel	1	3	4
Mexico	36	51	49
Netherlands	0	1	1
Russia	26	25	20
Switzerland	3	2	3
Taiwan	15	11	13
United Kingdom	5	4	4
United States	47	49	50

Reporting group values	Placebo Maximum Extended Enrollment (MEE)	2 mg Baricitinib (MEE)	4 mg Baricitinib (MEE)
Number of subjects	21	20	20
Age categorical Units: Subjects			
Age continuous			
Analysis Population Description (APD): All randomized participants who received at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: years			
arithmetic mean	32.90	37.70	34.60
standard deviation	± 10.83	± 11.38	± 8.31

Gender categorical			
APD: All randomized participants who receive at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: Subjects			
Female	20	19	20
Male	1	1	0
Ethnicity (NIH/OMB)			
APD: All randomized participants who receive at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	0	0
Unknown or Not Reported	21	20	20
Race (NIH/OMB)			
APD: All randomized participants who receive at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	21	20	20
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment			
APD: All randomized participants who receive at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: Subjects			
Australia	0	0	0
Austria	0	0	0
Belgium	0	0	0
Brazil	0	0	0
China	21	20	20
Croatia	0	0	0
Czechia	0	0	0
Germany	0	0	0
Greece	0	0	0
Hungary	0	0	0
Israel	0	0	0
Mexico	0	0	0
Netherlands	0	0	0
Russia	0	0	0
Switzerland	0	0	0
Taiwan	0	0	0
United Kingdom	0	0	0
United States	0	0	0

Reporting group values	Total		
Number of subjects	821		

Age categorical Units: Subjects			

Age continuous			
Analysis Population Description (APD): All randomized participants who received at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: years arithmetic mean standard deviation	- -		
Gender categorical			
APD: All randomized participants who receive at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: Subjects			
Female	771		
Male	50		
Ethnicity (NIH/OMB)			
APD: All randomized participants who receive at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: Subjects			
Hispanic or Latino	28		
Not Hispanic or Latino	115		
Unknown or Not Reported	678		
Race (NIH/OMB)			
APD: All randomized participants who receive at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: Subjects			
American Indian or Alaska Native	34		
Asian	167		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	89		
White	517		
More than one race	3		
Unknown or Not Reported	11		
Region of Enrollment			
APD: All randomized participants who receive at least one dose of study drug. One investigational site with seven participants was excluded from analysis due to confirmed misconduct.			
Units: Subjects			
Australia	31		
Austria	3		
Belgium	4		
Brazil	83		
China	116		
Croatia	10		
Czechia	38		
Germany	45		
Greece	18		
Hungary	50		
Israel	8		

Mexico	136		
Netherlands	2		
Russia	71		
Switzerland	8		
Taiwan	39		
United Kingdom	13		
United States	146		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received two placebo tablets: one matching 4 mg Baricitinib and one matching 2 mg Baricitinib administered orally every day (QD) for 52 weeks.	
Reporting group title	2 mg Baricitinib
Reporting group description:	
Participants received one 2 mg Baricitinib tablet and one placebo tablet matching 4 mg Baricitinib administered orally QD for 52 weeks.	
Reporting group title	4 mg Baricitinib
Reporting group description:	
Participants received one 4 mg Baricitinib tablet and one placebo tablet matching 2 mg Baricitinib administered orally every day (QD) for 52 weeks.	
Reporting group title	Placebo Maximum Extended Enrollment (MEE)
Reporting group description:	
Participants received two placebo tablets: one matching 4 mg Baricitinib and one matching 2 mg Baricitinib administered orally QD for 52 weeks.	
Reporting group title	2 mg Baricitinib (MEE)
Reporting group description:	
Participants received one 2 mg Baricitinib tablet and 1 placebo tablet matching 4 mg Baricitinib administered QD for 52 weeks.	
Reporting group title	4 mg Baricitinib (MEE)
Reporting group description:	
Participants received one 4 mg Baricitinib tablet and one placebo tablet matching 2 mg Baricitinib administered orally QD for 52 weeks.	
Subject analysis set title	2 mg Baricitinib
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Participants received one Baricitinib 2 mg tablet and one placebo tablet matching Baricitinib 4 mg administered orally QD for 52 weeks.	
Subject analysis set title	4 mg Baricitinib
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Participants received one Baricitinib 4 mg tablet and one placebo tablet matching baricitinib 2 mg administered orally QD for 52 weeks.	

Primary: Percentage of Participants Achieving a Systemic Lupus Erythematosus Responder Index 4 (SRI-4) Response (4 mg Baricitinib)

End point title	Percentage of Participants Achieving a Systemic Lupus Erythematosus Responder Index 4 (SRI-4) Response (4 mg Baricitinib)[1]
End point description:	
SRI-4 response defined as 1)greater than or equal to (>=) 4-point reduction in Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) total score 2)no new British Isles Lupus Assessment Group (BILAG) A and no more than 1 new BILAG B domain score and 3)no worsening in Physician Global Assessment (PGA) of Disease Activity (worsening defined as an increase of >=0.3 from baseline on a 0-3 visual analogue scale). SLEDAI-2K assessment consists of 24 items with total score of 0(no symptoms) to 105 (presence of all defined symptoms) with higher scores representing increased disease activity. BILAG Index: assessing clinical signs, symptoms,or laboratory parameters related to Systemic Lupus Erythematosus (SLE),divided into 9 organ systems. For each organ system A=severe disease,B=moderate disease,C=mild stable disease,D=inactive,but previously active,E=inactive and never affected. PGA assess disease activity on a visual analogue scale from 0 to 3 (1=mild, 2=moderate, 3=severe).	
End point type	Primary

End point timeframe:

Week 52
APD: All randomized participants who received at least one dose of study drug (modified intent-to-treat (mITT) population). Missing data was imputed using the hybrid imputation method [nonresponder imputation (NRI) + multiple imputation (MI)].

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis is planned only for these reporting arms.
As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point values	Placebo	4 mg Baricitinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	253	252		
Units: percentage of participants				
number (not applicable)	45.9	56.7		

Statistical analyses

Statistical analysis title	SRI-4 Response (4 mg)
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	505
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.016
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.09
upper limit	2.27

Secondary: Percentage of Participants Achieving SRI-4 Response - 2 mg Baricitinib

End point title	Percentage of Participants Achieving SRI-4 Response - 2 mg Baricitinib[2]

End point description:

SRI-4 response defined as 1)greater than or equal to (>=) 4-point reduction in Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) total score 2)no new British Isles Lupus Assessment Group (BILAG) A and no more than 1 new BILAG B domain score and 3)no worsening in Physician Global Assessment (PGA) of Disease Activity (worsening defined as an increase of >=0.3 from baseline on a 0-3 visual analogue scale).
SLEDAI-2K assessment consists of 24 items with total score of 0(no symptoms) to 105 (presence of all defined symptoms) with higher scores representing increased disease activity. BILAG Index: assessing clinical signs, symptoms,or laboratory parameters related to Systemic Lupus Erythematosus (SLE),divided into 9 organ systems. For each organ system A=severe disease,B=moderate disease,C=mild stable disease,D=inactive,but previously active,E=inactive and never affected. PGA assess disease activity on a visual analogue scale from 0 to 3 (1=mild, 2=moderate, 3=severe).

End point type	Secondary

End point timeframe:

Week 52
APD: All randomized participants who receive at least one dose of study drug (mITT population). Missing data was imputed using the hybrid imputation method [nonresponder imputation (NRI) + multiple imputation (MI)].

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis is planned only for these reporting arms.
As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point values	Placebo	2 mg Baricitinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	253	255		
Units: percentage of participants				
number (not applicable)	45.9	49.8		

Statistical analyses

Statistical analysis title	SRI-4 Response (2 mg)
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	508
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.47
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.65

Secondary: Percentage of Participants Achieving a Lupus Low Disease Activity State (LLDAS)

End point title	Percentage of Participants Achieving a Lupus Low Disease Activity State (LLDAS)[3]

End point description:

The LLDAS is a composite measure designed to identify patients achieving a state of low disease activity. The LLDAS response criteria were: (1) SLEDAI-2K <=4, with no activity in major organ systems (CNS, vascular, renal, cardiorespiratory and constitutional); where "no activity" is defined as all items of SLEDAI-2K within these major organ systems equal to 0. (2)no new features of lupus disease activity compared to previous occurred visit, where the "new feature" is defined as any of the SLEDAI-2K 24 items changed from 0 to greater than 0; (3) PGA (scale 0-3), <=1; (4) current prednisolone (or equivalent) dose <=7.5 mg daily.
APD: All randomized participants who receive at least one dose of study drug (mITT population). Missing data was imputed using the hybrid imputation method [nonresponder imputation (NRI) + multiple imputation (MI)].

End point type	Secondary

End point timeframe:

Week 52

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point values	Placebo	2 mg Baricitinib	4 mg Baricitinib	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	253	255	252	
Units: percentage of participants				
number (not applicable)	26.2	25.7	29.7	

Statistical analyses

Statistical analysis title	Lupus Low Disease Activity State (2 mg)
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	508
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.839
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.45

Statistical analysis title	Lupus Low Disease Activity State (4 mg)
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	505
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.391
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.79

Secondary: Time to First Severe Flare

End point title	Time to First Severe Flare[4]

End point description:

Time to first severe flare was analyzed using a Cox proportional hazards model with treatment group, baseline disease activity (Systemic Lupus Erythematosus Disease Activity Index 2000 [SLEDAI-2K] <10; SLEDAI-2K ≥10), baseline corticosteroid dose (<10 mg/day; ≥10 mg/day prednisone or equivalent), and region fitted as explanatory variables. Participants who did not have severe flare during the flare exposure time period were censored at the end of the flare exposure time.

APD: All randomized participants who receive at least one dose of study drug (mITT population). 9999=Data Not Available (N/A) as < 50% of participants experienced first flare, median was not reached, and 95% confidence interval could not be calculated.

End point type	Secondary

End point timeframe:

Baseline to Week 52

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point values	Placebo	2 mg Baricitinib	4 mg Baricitinib	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	253	255	252	
Units: weeks				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Whose Average Prednisone Dose Had Been Reduced by >=25% From Baseline to <=7.5 mg/Day During Weeks 40 Through 52 in Participants Receiving Greater Than 7.5 mg/Day at Baseline

End point title	Percentage of Participants Whose Average Prednisone Dose Had Been Reduced by >=25% From Baseline to <=7.5 mg/Day During Weeks 40 Through 52 in Participants Receiving Greater Than 7.5 mg/Day at Baseline[5]

End point description:

For the analysis of steroid use, steroid dosages were converted to a prednisone equivalent in mg. A responder was defined as having a prednisone reduction by >=25% from Baseline to <=7.5 mg/day during Weeks 40 through 52.

APD: All randomized participants who received at least one dose of study drug (mITT population) and received >7.5 mg prednisone at baseline. Missing data was imputed using the hybrid imputation method [NRI + mLOCF (modified last observation carried forward)].

End point type	Secondary

End point timeframe:

Baseline, Week 40 through Week 52

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point values	Placebo	2 mg Baricitinib	4 mg Baricitinib	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	117	106	106	
Units: percentage of participants				
number (not applicable)	30.8	29.2	34.0	

Statistical analyses

Statistical analysis title	Prednisone Dose Reduction (2 mg)
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	223
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.82
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.66

Statistical analysis title	Prednisone Reduction (4 mg)
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	223
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.565
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	2.08

Secondary: Change from Baseline in Worst Pain Numeric Rating Scale (NRS)

End point title	Change from Baseline in Worst Pain Numeric Rating Scale (NRS)[6]

End point description:

Participants assessed their worst pain in the last 24 hours on an 11-point numeric rating scale (NRS) ranging from 0 (no pain) to 10 (pain as bad as you can imagine). The average worst daily pain score was calculated as the mean of the scores over the last 7 days prior to each assessment time point. Higher score indicated severe pain. Least Squares (LS) mean was calculated using Mixed Model Repeated Measures (MMRM) analysis with treatment, baseline disease activity (total SLEDAI-2K <10; >=10), baseline corticosteroid dose (<10 mg/day; >= 10 mg/day prednisone or equivalent), region (North America, Central/South, America/Mexico, Europe, Asia Rest of World), visit (as categorical variable), baseline value, treatment-by-visit interaction, and baseline value-by-visit interaction.

End point type	Secondary

End point timeframe:

Baseline, Week 52
APD: All randomized participants who received at least 1 dose of study drug (mITT population) and had baseline and post-baseline values at the specified time point. Missing data was imputed using the hybrid imputation method NRI + MMRM.

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point values	Placebo	2 mg Baricitinib	4 mg Baricitinib	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	173	173	182	
Units: score on a scale				
least squares mean (standard error)	-1.62 (± 0.15)	-1.73 (± 0.15)	-1.71 (± 0.15)	

Statistical analyses

Statistical analysis title	Change from Baseline in Worst Pain NRS (2 mg)
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	346
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.598
Method	Mixed models analysis
Parameter estimate	LS Mean Difference Final Values
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.52
upper limit	0.3
Variability estimate	Standard error of the mean
Dispersion value	0.21

Statistical analysis title	Change from Baseline in Worst Pain NRS (4 mg)
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	355
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.674
Method	Mixed models analysis
Parameter estimate	LS Mean Difference Final Values
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	0.32
Variability estimate	Standard error of the mean
Dispersion value	0.21

Secondary: Change from Baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) Total Score

End point title	Change from Baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) Total Score[7]

End point description:

FACIT-Fatigue score calculated according to a 13-item questionnaire that assess self reported fatigue and its impact upon daily activities and function. It uses a 5-point Likert-type scale (0 = not at all; 1 = a little bit; 2 = somewhat; 3 = quite a bit; 4 = very much). The sum of all responses resulted in the FACIT-Fatigue score for a total possible score of 0 (worse possible score) to 52 (best score). A higher score reflected an improvement in the participant's health status. Least Squares (LS) mean was calculated using MMRM analysis with treatment, baseline disease activity (total SLEDAI-2K <10; >=10), baseline corticosteroid dose (<10 mg/day; >= 10 mg/day prednisone or equivalent), region (North America, Central/South, America/Mexico, Europe, Asia Rest of World), visit (as categorical variable), baseline value, treatment-by-visit interaction, and baseline value-by-visit interaction.

End point type	Secondary

End point timeframe:

Baseline, Week 52
APD: All randomized participants who received at least one dose of study drug (mITT population) and had baseline and post-baseline values at the specified time point. Missing data was imputed using hybrid the imputation method NRI+MMRM.

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point values	Placebo	2 mg Baricitinib	4 mg Baricitinib	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	188	201	204	
Units: score on a scale				
least squares mean (standard error)	7.44 (± 0.62)	7.46 (± 0.60)	7.08 (± 0.61)	

Statistical analyses

Statistical analysis title	Change from Baseline in FACIT-Fatigue (2 mg)
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	389
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.979
Method	Mixed models analysis
Parameter estimate	LS Mean Difference Final Values
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.65
upper limit	1.7
Variability estimate	Standard error of the mean
Dispersion value	0.85

Statistical analysis title	Change from Baseline in FACIT-Fatigue (4 mg)
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	392
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.678
Method	Mixed models analysis
Parameter estimate	LS Mean Difference Final Values
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.03
upper limit	1.32
Variability estimate	Standard error of the mean
Dispersion value	0.86

Secondary: Percentage of Participants with Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) Total Activity Score ≥10 at Baseline with ≥50% Reduction in CLASI Total Activity Score

End point title	Percentage of Participants with Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) Total Activity Score ≥10 at Baseline with ≥50% Reduction in CLASI Total Activity Score[8]

End point description:

The CLASI is a single-page tool that separately quantifies disease activity and damage. For the activity score, points are given for the presence of erythema, scale, mucous membrane lesions, recent hair loss, and inflammatory alopecia. The total score represents the sum of the individual scores and ranges from 0 to 70. Higher scores are awarded for more severe manifestations.
APD: All randomized participants who received at least one dose of study drug (mITT population) and

had baseline CLASI score of >= 10. Missing data was imputed using NRI method.

End point type	Secondary

End point timeframe:

Week 52

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point values	Placebo	2 mg Baricitinib	4 mg Baricitinib	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	46	43	
Units: percentage of participants				
number (not applicable)	49.0	54.3	55.8	

Statistical analyses

Statistical analysis title	50% Reduction in CLASI Score (2 mg)
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.965
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	2.42

Statistical analysis title	50% Reduction in CLASI Score (4 mg)
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.661
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	2.92

Secondary: Change from Baseline in Tender Joint Count

End point title	Change from Baseline in Tender Joint Count[9]

End point description:

The number of tender and painful joints is determined by examination of 28 joints (14 on each side) which include: the 2 shoulders, the 2 elbows, the 2 wrists, the 10 metacarpophalangeal joints, the 2 interphalangeal joints of the thumb, the 8 proximal interphalangeal joints, and the 2 knees. The joints are assessed and classified as tender or not tender. LS mean was calculated using Mixed Model Repeated Measures (MMRM) analysis with treatment, baseline disease activity (total SLEDAI-2K <10; >=10), baseline corticosteroid dose (<10 mg/day; >=10 mg/day prednisone or equivalent), region (North America, Central/South America/Mexico, Europe, Asia and Rest of World), visit (as categorical variable), baseline value, treatment-by-visit interaction, and baseline value-by-visit interaction.
APD: All randomized participants who receive at least one dose of study drug (mITT population) and had baseline and post-baseline values at specified time point.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point values	Placebo	2 mg Baricitinib	4 mg Baricitinib	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183	198	195	
Units: tender joint count				
least squares mean (standard error)	-7.50 (± 0.312)	-7.26 (± 0.305)	-7.94 (± 0.307)	

Statistical analyses

Statistical analysis title	Change from Baseline Tender Joint Count (2 mg)
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	381
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.578
Method	Mixed models analysis
Parameter estimate	LS Mean Difference Final Values
Point estimate	0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.61
upper limit	1.08
Variability estimate	Standard error of the mean
Dispersion value	0.43

Statistical analysis title	Change from Baseline Tender Joint Count (4 mg)
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.309
Method	Mixed models analysis
Parameter estimate	LS Mean Difference Final Values
Point estimate	-0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.29
upper limit	0.41
Variability estimate	Standard error of the mean
Dispersion value	0.433

Secondary: Change from Baseline in Swollen Joint Count

End point title	Change from Baseline in Swollen Joint Count[10]

End point description:

The number of swollen joints is determined by examination of 28 joints (14 on each side) which include: the 2 shoulders, the 2 elbows, the 2 wrists, the 10 metacarpophalangeal joints, the 2 interphalangeal joints of the thumb, the 8 proximal interphalangeal joints, and the 2 knees. The joints are assessed and classified as swollen or not swollen. LS mean was calculated using MMRM analysis with treatment, baseline disease activity (total SLEDAI-2K <10; >=10), baseline corticosteroid dose (<10 mg/day; >=10 mg/day prednisone or equivalent), region (North America, Central/South America/Mexico, Europe, Asia and Rest of World), visit (as categorical variable), baseline value, treatment-by-visit interaction, and baseline value-by-visit interaction.
APD: All randomized participants who receive at least one dose of study drug (mITT population) and had baseline and post-baseline values at the specified time point.

End point type	Secondary

End point timeframe:

Baseline, Week 52

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point values	Placebo	2 mg Baricitinib	4 mg Baricitinib	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183	198	195	
Units: swollen joint count				
least squares mean (standard error)	-5.37 (± 0.201)	-5.67 (± 0.196)	-5.81 (± 0.198)	

Statistical analyses

Statistical analysis title	Change from Baseline in Swollen Joint Count (2 mg)
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	381
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.287
Method	Mixed models analysis
Parameter estimate	LS Mean Difference Final Values
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.84
upper limit	0.25
Variability estimate	Standard error of the mean
Dispersion value	0.277

Statistical analysis title	Change from Baseline in Swollen Joint Count (4 mg)
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.113
Method	Mixed models analysis
Parameter estimate	LS Mean Difference Final Values
Point estimate	-0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.99
upper limit	0.11
Variability estimate	Standard error of the mean
Dispersion value	0.278

Secondary: Population Pharmacokinetics (PK): Area Under the Concentration-Time Curve of Baricitinib at Steady State ($AUC_{T, ss}$)

End point title	Population Pharmacokinetics (PK): Area Under the Concentration-Time Curve of Baricitinib at Steady State (AUC_{T}, ss)

End point description:

PK: Area Under the Concentration-Time Curve of Baricitinib at Steady State ($AUC_{T, ss}$) was evaluated using population PK approach.
APD: All randomized participants who received at least one dose of study drug and had evaluable PK data. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

Week 0 (Baseline): 15 minutes (min) and 60 min postdose; Week 4: 2 to 4 hours (hr) postdose; Week 8: 4 to 6 hr postdose; Week 12 and Week 16 predose

End point values	2 mg Baricitinib	4 mg Baricitinib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	248	220		
Units: hour*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)	256 (± 52)	502 (± 52)		

Statistical analyses

No statistical analyses for this end point

Secondary: Population PK: Maximum Observed Drug Concentration at Steady State (Cmax,ss)

End point title	Population PK: Maximum Observed Drug Concentration at Steady State (Cmax,ss)

End point description:

Population PK: Maximum Observed Drug Concentration at Steady State (Cmax,ss) was evaluated using population PK approach.
APD: All randomized participants who received at least one dose of study drug and had evaluable PK data. As pre-specified in the analysis plan, outcome measures will not be reported for the MEE arms/groups but only for the main global study arms/groups.

End point type	Secondary

End point timeframe:

Week 0 (Baseline): 15 minutes (min) and 60 min postdose; Week 4: 2 to 4 hours (hr) postdose; Week 8: 4 to 6 hr postdose; Week 12 and Week 16 predose

End point values	2 mg Baricitinib	4 mg Baricitinib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	248	220		
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	26.7 (± 24)	53.0 (± 23)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline through Follow-up (Up to 56 Weeks)
One investigational site with seven participants was excluded from analysis due to confirmed misconduct.

Adverse event reporting additional description:

All randomized participants who received at least one dose of investigational product and who did not discontinue from the study for the reason "Lost to Follow-up" at the first postbaseline visit. Gender specific events occurring only 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	24.0

Reporting groups

Reporting group title	Placebo

Reporting group description:

Participants received two placebo tablets: one matching baricitinib 4 mg and one matching baricitinib 2 mg administered orally QD for 52 weeks.

Reporting group title	2 mg Baricitinib

Reporting group description:

Participants received one Baricitinib 2 mg tablet and one placebo tablet matching Baricitinib 4 mg administered QD for 52 weeks.

Reporting group title	4 mg Baricitinib

Reporting group description:

Participants received one Baricitinib 4 mg tablet and one placebo tablet matching baricitinib 2 mg administered orally QD for 52 weeks.

Reporting group title	Placebo Maximum Extended Enrollment (MEE)

Reporting group description:

Participants received two placebo tablets: one matching baricitinib 4 mg and one matching baricitinib 2 mg administered orally QD for 52 weeks

Reporting group title	2 mg Baricitinib (MEE)

Reporting group description:

Participants received one Baricitinib 2 mg tablet and 1 placebo tablet matching Baricitinib 4 mg administered QD for 52 weeks.

Reporting group title	4 mg Baricitinib (MEE)

Reporting group description:

Participants received one Baricitinib 4 mg tablet and one placebo tablet matching baricitinib 2 mg administered orally QD for 52 weeks.

Serious adverse events	Placebo	2 mg Baricitinib	4 mg Baricitinib
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 253 (7.51%)	27 / 255 (10.59%)	31 / 252 (12.30%)
number of deaths (all causes)	1	1	0
number of deaths resulting from adverse events	0	1	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma of the cervix			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[1]	1 / 237 (0.42%)	0 / 238 (0.00%)	0 / 237 (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
burkitt's lymphoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
haemangioma of liver			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	0 / 252 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung carcinoma cell type unspecified stage 0			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
melanocytic naevus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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
papillary thyroid cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used:			

MedDRA 24.0			
subjects affected / exposed[2]	1 / 237 (0.42%)	0 / 238 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
vasculitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[3]	0 / 237 (0.00%)	0 / 238 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
death			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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
Reproductive system and breast disorders			
adnexal torsion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[4]	0 / 237 (0.00%)	0 / 238 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervical dysplasia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[5]	0 / 237 (0.00%)	0 / 238 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hydrosalpinx			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[6]	0 / 237 (0.00%)	1 / 238 (0.42%)	0 / 237 (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
ovarian cyst			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[7]	1 / 237 (0.42%)	0 / 238 (0.00%)	0 / 237 (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			

bronchitis chronic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
pleural effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	1 / 255 (0.39%)	0 / 252 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleurisy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
pulmonary hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	0 / 252 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
major depression			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	2 / 252 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device use issue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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
femur fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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
fibula fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	1 / 255 (0.39%)	0 / 252 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
pericarditis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebrovascular accident			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukopenia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutropenia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal adhesions			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
abdominal pain lower			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epiploic appendagitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis erosive			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematochezia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
obstructive pancreatitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatobiliary disorders			
bile duct stone			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
cholecystitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
cholecystitis chronic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	0 / 252 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
Skin and subcutaneous tissue disorders			
cutaneous lupus erythematosus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
dermatitis bullous			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
lupus nephritis			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	2 / 255 (0.78%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ureterolithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	0 / 252 (0.00%)
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 stenosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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
systemic lupus erythematosus			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 253 (0.40%)	1 / 255 (0.39%)	4 / 252 (1.59%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
anal abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis bacterial			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atypical pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
covid-19			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
covid-19 pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
escherichia urinary tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	0 / 252 (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
herpes zoster			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laryngitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	4 / 255 (1.57%)	2 / 252 (0.79%)
occurrences causally related to treatment / all	0 / 0	3 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tubo-ovarian abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[8]	0 / 237 (0.00%)	1 / 238 (0.42%)	0 / 237 (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
viral myocarditis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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
viral pericarditis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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
hypoalbuminaemia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	0 / 252 (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

Serious adverse events	Placebo Maximum Extended Enrollment (MEE)	2 mg Baricitinib (MEE)	4 mg Baricitinib (MEE)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 21 (4.76%)	4 / 20 (20.00%)	3 / 20 (15.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma of the cervix			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[1]	0 / 20 (0.00%)	0 / 19 (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
burkitt's lymphoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
haemangioma of liver			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 20 (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
lung carcinoma cell type unspecified stage 0			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
melanocytic naevus			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
papillary thyroid cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[2]	0 / 20 (0.00%)	0 / 19 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
vasculitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[3]	0 / 20 (0.00%)	0 / 19 (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
General disorders and administration site conditions			
death			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
pyrexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
Reproductive system and breast disorders			
adnexal torsion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[4]	0 / 20 (0.00%)	0 / 19 (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
cervical dysplasia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[5]	0 / 20 (0.00%)	0 / 19 (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
hydrosalpinx			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed[6]	0 / 20 (0.00%)	0 / 19 (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
ovarian cyst			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[7]	0 / 20 (0.00%)	0 / 19 (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
Respiratory, thoracic and mediastinal disorders			
bronchitis chronic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
pleural effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
pleurisy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
pulmonary embolism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
pulmonary hypertension			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 20 (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
Psychiatric disorders			
major depression			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
device use issue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
femur fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
fibula fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
foot fracture			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
tendon rupture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
atrial fibrillation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
coronary artery disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
myocardial ischaemia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
pericarditis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
Nervous system disorders			
cerebrovascular accident			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
leukopenia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
neutropenia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
Gastrointestinal disorders			
abdominal adhesions			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
abdominal pain lower			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
epiploic appendagitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
gastric ulcer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
gastritis erosive			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
haematochezia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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

obstructive pancreatitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
Hepatobiliary disorders			
bile duct stone			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
cholecystitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
cholecystitis chronic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
cutaneous lupus erythematosus			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
dermatitis bullous			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
Renal and urinary disorders			
lupus nephritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 20 (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
ureterolithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
osteoarthritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
osteonecrosis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 20 (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
spinal stenosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
systemic lupus erythematosus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
anal abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
appendicitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
arthritis bacterial			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
atypical pneumonia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
bronchitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
covid-19 pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
escherichia urinary tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
gastroenteritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
herpes zoster			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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

infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
laryngitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
pyelonephritis acute			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
tubo-ovarian abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[8]	0 / 20 (0.00%)	0 / 19 (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
viral myocarditis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
viral pericarditis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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
hypoalbuminaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (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

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 occurring only 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 occurring only 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 occurring only 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 occurring only 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 occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[6] - 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 occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[7] - 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 occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[8] - 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 occurring only 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	2 mg Baricitinib	4 mg Baricitinib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	129 / 253 (50.99%)	144 / 255 (56.47%)	144 / 252 (57.14%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	10 / 253 (3.95%)	17 / 255 (6.67%)	17 / 252 (6.75%)
occurrences (all)	10	18	18
General disorders and administration site conditions			
chest discomfort			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	0 / 255 (0.00%)	4 / 252 (1.59%)
occurrences (all)	0	0	4
Reproductive system and breast disorders			
prostatitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[9]	0 / 16 (0.00%)	1 / 17 (5.88%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	7 / 253 (2.77%)	5 / 255 (1.96%)	7 / 252 (2.78%)
occurrences (all)	7	5	7
Psychiatric disorders			
insomnia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	8 / 253 (3.16%)	4 / 255 (1.57%)	5 / 252 (1.98%)
occurrences (all)	8	4	6
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	7 / 253 (2.77%)	6 / 255 (2.35%)	2 / 252 (0.79%)
occurrences (all)	7	8	5
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	3 / 253 (1.19%)	8 / 255 (3.14%)	14 / 252 (5.56%)
occurrences (all)	4	9	20
hepatic enzyme increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	2 / 252 (0.79%)
occurrences (all)	1	0	2
weight increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	7 / 253 (2.77%)	5 / 255 (1.96%)	3 / 252 (1.19%)
occurrences (all)	9	5	3
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 253 (1.58%)	1 / 255 (0.39%)	5 / 252 (1.98%)
occurrences (all)	4	1	6
headache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	25 / 253 (9.88%)	16 / 255 (6.27%)	20 / 252 (7.94%)
occurrences (all)	26	19	23
hypoaesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	1 / 255 (0.39%)	2 / 252 (0.79%)
occurrences (all)	0	1	2
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 253 (1.58%)	4 / 255 (1.57%)	13 / 252 (5.16%)
occurrences (all)	4	6	16
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	4 / 255 (1.57%)	0 / 252 (0.00%)
occurrences (all)	0	4	0
lymphopenia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	10 / 253 (3.95%)	11 / 255 (4.31%)	9 / 252 (3.57%)
occurrences (all)	13	14	10
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	2 / 255 (0.78%)	3 / 252 (1.19%)
occurrences (all)	1	2	4
diarrhoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	10 / 253 (3.95%)	10 / 255 (3.92%)	10 / 252 (3.97%)
occurrences (all)	12	12	12
gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	4 / 255 (1.57%)	2 / 252 (0.79%)
occurrences (all)	1	4	2
mouth ulceration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	2 / 255 (0.78%)	1 / 252 (0.40%)
occurrences (all)	1	2	1
nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 253 (1.98%)	11 / 255 (4.31%)	12 / 252 (4.76%)
occurrences (all)	5	13	14
toothache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	5 / 255 (1.96%)	3 / 252 (1.19%)
occurrences (all)	1	5	3
Hepatobiliary disorders			
hepatic function abnormal			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 253 (0.00%)	3 / 255 (1.18%)	0 / 252 (0.00%)
occurrences (all)	0	3	0
Skin and subcutaneous tissue disorders			
urticaria			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	3 / 253 (1.19%)	3 / 255 (1.18%)	4 / 252 (1.59%)
occurrences (all)	3	3	4
Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	1 / 255 (0.39%)	0 / 252 (0.00%)
occurrences (all)	1	1	0
Infections and infestations			
covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 253 (3.56%)	16 / 255 (6.27%)	13 / 252 (5.16%)
occurrences (all)	9	16	13
gingivitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	0 / 255 (0.00%)	1 / 252 (0.40%)
occurrences (all)	1	0	1
herpes zoster			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	8 / 253 (3.16%)	9 / 255 (3.53%)	16 / 252 (6.35%)
occurrences (all)	8	9	18
nasopharyngitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	17 / 253 (6.72%)	19 / 255 (7.45%)	18 / 252 (7.14%)
occurrences (all)	24	21	24
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	17 / 253 (6.72%)	21 / 255 (8.24%)	19 / 252 (7.54%)
occurrences (all)	19	30	27
urinary tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	25 / 253 (9.88%)	32 / 255 (12.55%)	37 / 252 (14.68%)
occurrences (all)	38	41	47
vulvitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed[10]	0 / 237 (0.00%)	0 / 238 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
hyperlipidaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	2 / 255 (0.78%)	6 / 252 (2.38%)
occurrences (all)	1	2	6
hypertriglyceridaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 253 (1.58%)	9 / 255 (3.53%)	3 / 252 (1.19%)
occurrences (all)	5	9	3
hyperuricaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 253 (0.40%)	2 / 255 (0.78%)	2 / 252 (0.79%)
occurrences (all)	2	2	2

Non-serious adverse events	Placebo Maximum Extended Enrollment (MEE)	2 mg Baricitinib (MEE)	4 mg Baricitinib (MEE)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 21 (80.95%)	14 / 20 (70.00%)	17 / 20 (85.00%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
General disorders and administration site conditions			
chest discomfort			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
Reproductive system and breast disorders			
prostatitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[9]	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal			

disorders			
cough			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
Psychiatric disorders			
insomnia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 21 (4.76%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
hepatic enzyme increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
weight increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 21 (9.52%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	4	1	1
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	3 / 20 (15.00%)
occurrences (all)	0	1	4
headache			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	3	1	1
hypoaesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	4	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 21 (14.29%)	2 / 20 (10.00%)	2 / 20 (10.00%)
occurrences (all)	4	2	2
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	2 / 20 (10.00%)
occurrences (all)	2	0	2
lymphopenia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 21 (14.29%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	3	1	1
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 21 (4.76%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	1	4	0
diarrhoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 21 (4.76%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	1	2	1
gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
mouth ulceration			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
toothache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 21 (9.52%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	2	1	2
Hepatobiliary disorders			
hepatic function abnormal			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	2	2
Skin and subcutaneous tissue disorders			
urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
gingivitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	4	1
herpes zoster			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
nasopharyngitis alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
upper respiratory tract infection alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 21 (23.81%)	9 / 20 (45.00%)	7 / 20 (35.00%)
occurrences (all)	11	17	8
urinary tract infection alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 21 (9.52%)	3 / 20 (15.00%)	1 / 20 (5.00%)
occurrences (all)	2	3	1
vulvitis alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[10]	0 / 20 (0.00%)	1 / 19 (5.26%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
hyperlipidaemia alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 21 (14.29%)	4 / 20 (20.00%)	3 / 20 (15.00%)
occurrences (all)	4	4	3
hypertriglyceridaemia alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 21 (23.81%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences (all)	5	0	1
hyperuricaemia alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 21 (9.52%)	3 / 20 (15.00%)	4 / 20 (20.00%)
occurrences (all)	3	3	4

Notes:

[9] - 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 occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.

[10] - 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 occurring only 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
07 December 2018	- Modified logistic regression analyses; - Clarified the definition of post-menopausal; - Data from types of chest imaging other than x-ray can be accepted for tuberculosis screening; - Arterial thromboembolic events (ATEs) adjudicated by a blinded clinical event committee; - Analysis Methods were revised; - Language was revised for missing data imputation; - Subgroup analysis has been removed from the protocol.
20 April 2020	- Participant number and statistical analysis was revised to account for COVID-19 affected participants; - Protocol updated to include provisions put into place in order to assure the safety of trial participants and minimizing risks to trial integrity during the COVID-19 pandemic; - Schedule of activities was clarified; - Analysis of British Isles Lupus Assessment Group Based Composite Lupus Assessment (BICLA) endpoint was included in the protocol to supplement efficacy analyses; - Updated to clarify that while most concomitant medications should remain stable during the trial, reductions in dose for safety are permitted; - Updated to clarify that prohibited use of corticosteroids for SLE requires discontinuation from study drug, while use of prohibited doses of corticosteroids for other reasons may not require discontinuation of study drug; - An interim analysis has been added to assess the likelihood of trial failure time prior to trial conclusion in order to minimize participant exposure to an ineffective drug.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

One investigational site with seven participants was excluded from analysis due to confirmed misconduct.
Study terminated due to insufficient evidence to support a positive benefit: risk profile in systemic lupus erythematosus patients.

Notes: