Clinical trial results:
A Phase 3b, Multicenter, Open-Label Study to Evaluate the Long-Term Safety and Efficacy of LY2127399 in Patients with Rheumatoid Arthritis (RA)

Summary

EudraCT number	2010-022208-36
Trial protocol	HU DE LT ES IT BG PL GR
Global end of trial date	24 March 2014

Results information

Result version number	v1 (current)
This version publication date	09 April 2018
First version publication date	09 April 2018

Trial information

Trial identification

Sponsor protocol code	H9B-MC-BCDP

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01215942
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 13419

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, 1 877-CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-285-4559,

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	24 March 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 March 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary purpose of this study is to help answer if LY2127399 is safe and effective during long-term treatment in participants with Rheumatoid Arthritis.

This study is comprised of 2 periods:

Period 1: Unblinded treatment for up to 240 weeks for participants who enroll from Study H9B-MC-BCDO (BCDO) (EU#2010-022206-40)) or Study H9B-MC-BCDV (BCDV) (EU#2010-022207-22) or up to 168 weeks for participants who enroll from Study H9B-MC-BCDM (BCDM) (EU#2010-022205-17).

Period 2: 48-week post-treatment follow-up

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	22 June 2011
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 442
Country: Number of subjects enrolled	Taiwan: 20
Country: Number of subjects enrolled	Slovakia: 12
Country: Number of subjects enrolled	Greece: 2
Country: Number of subjects enrolled	Ukraine: 33
Country: Number of subjects enrolled	Russian Federation: 33
Country: Number of subjects enrolled	Colombia: 35
Country: Number of subjects enrolled	Sri Lanka: 9
Country: Number of subjects enrolled	India: 20
Country: Number of subjects enrolled	Malaysia: 4
Country: Number of subjects enrolled	Australia: 10
Country: Number of subjects enrolled	South Africa: 82

Country: Number of subjects enrolled	Korea, Republic of: 17
Country: Number of subjects enrolled	Lithuania: 31
Country: Number of subjects enrolled	Hungary: 14
Country: Number of subjects enrolled	Mexico: 43
Country: Number of subjects enrolled	Argentina: 23
Country: Number of subjects enrolled	Poland: 78
Country: Number of subjects enrolled	Brazil: 9
Country: Number of subjects enrolled	Croatia: 4
Country: Number of subjects enrolled	Romania: 3
Country: Number of subjects enrolled	Bulgaria: 24
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	Japan: 116
Country: Number of subjects enrolled	New Zealand: 18
Worldwide total number of subjects	1086
EEA total number of subjects	172

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	951
From 65 to 84 years	135
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Study consisted of a Treatment Period of up to 240 weeks for participants (pts) who enrolled from Studies H9B-MC-BCDO (BCDO) and H9B-MC-BCDV (BCDV) or up to 168 weeks for pts who enrolled from Study H9-MC-BCDM (BCDM). Discontinued pts were followed in Post-Treatment Follow-Up Period for up to 48 weeks.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	120 mg LY2127399 (LY A)

Arm description:

120 milligrams (mg) LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W). Participants from Studies BCDO, BCDV and BCDM who were on 120 mg LY2127399 SC Q4W immediately prior to Study H9B-MC-BCDP (BCDP) enrollment remained on 120 mg LY2127399 SC Q4W. Participants from Studies BCDO, BCDV and BCDM who were on placebo immediately prior to Study BCDP enrollment were randomized to receive a loading dose of 240 mg LY2127399 SC, 4 weeks later followed by 120 mg LY2127399 SC Q4W for the subsequent treatment.

Arm type	Experimental
Investigational medicinal product name	Tabalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

120 milligrams (mg) of LY2127399 Given every 4 weeks for 240 weeks for those participants from Study BCDO or Study BCDV. Participants who had been receiving placebo immediately prior to enrollment will receive a 240 mg loading dose when initiating treatment.

Or

Given every 4 weeks for 168 weeks for those participants from Study BCDM.

Arm title	90 mg LY2127399 (LY B)

Arm description:

90 mg LY2127399 administered SC every 2 weeks (Q2W).

Participants from Studies BCDO, BCDV and BCDM who were on 90 mg LY2127399 SC Q2W immediately prior to Study BCDP enrollment remained on 90 mg LY2127399 SC Q2W. Participants from Studies BCDO, BCDV and BCDM who were on placebo immediately prior to Study BCDP enrollment were randomized to receive a loading dose of 180 mg LY2127399 SC, 2 weeks later followed by 90 mg LY2127399 SC Q2W for the subsequent treatment.

Arm type	Experimental

Investigational medicinal product name	Tabalumab
Investigational medicinal product code	LY2127399
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

90 mg LY2127399 Given every 2 weeks for 240 weeks for those participants from Study BCDO or Study BCDV. Participants who had been receiving placebo immediately prior to enrollment will receive a 180 mg loading dose when initiating treatment.

Or

Given every 2 weeks for 168 weeks for those participants from Study BCDM.

Number of subjects in period 1	120 mg LY2127399 (LY A)	90 mg LY2127399 (LY B)
Started	414	672
One dose of study drug	414	672
Completed treatment period Wk 240	0 [1]	0 [2]
Entered Post-treatment follow-up	368	591
Completed	283	445
Not completed	131	227
Consent withdrawn by subject	83	140
Physician decision	1	2
Death	2	5
Lost to follow-up	15	17
Sponsor decision	28	61
Investigator site close	2	2

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No patients completed the 240-week (participants from BCDO and BCDV) or 168-week (participants from BCDM) Treatment Period before termination of the study. Participants who discontinued treatment were followed in post-treatment follow-up, however not all participants who discontinued treatment entered post-treatment follow-up period.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No patients completed the 240-week (participants from BCDO and BCDV) or 168-week (participants from BCDM)Treatment Period before termination of the study. Participants who discontinued treatment were followed in post-treatment follow-up, however not all participants who discontinued treatment entered post-treatment follow-up period.

Baseline characteristics

Reporting groups	
Reporting group title	120 mg LY2127399 (LY A)

Reporting group description:

120 milligrams (mg) LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W).
Participants from Studies BCDO, BCDV and BCDM who were on 120 mg LY2127399 SC Q4W immediately prior to Study H9B-MC-BCDP (BCDP) enrollment remained on 120 mg LY2127399 SC Q4W. Participants from Studies BCDO, BCDV and BCDM who were on placebo immediately prior to Study BCDP enrollment were randomized to receive a loading dose of 240 mg LY2127399 SC, 4 weeks later followed by 120 mg LY2127399 SC Q4W for the subsequent treatment.

Reporting group title	90 mg LY2127399 (LY B)

Reporting group description:

90 mg LY2127399 administered SC every 2 weeks (Q2W).

Participants from Studies BCDO, BCDV and BCDM who were on 90 mg LY2127399 SC Q2W immediately prior to Study BCDP enrollment remained on 90 mg LY2127399 SC Q2W. Participants from Studies BCDO, BCDV and BCDM who were on placebo immediately prior to Study BCDP enrollment were randomized to receive a loading dose of 180 mg LY2127399 SC, 2 weeks later followed by 90 mg LY2127399 SC Q2W for the subsequent treatment.

Reporting group values	120 mg LY2127399 (LY A)	90 mg LY2127399 (LY B)	Total
Number of subjects	414	672	1086
Age categorical Units: Subjects			
Gender, Male/Female Units:			
Female	339	538	877
Male	75	134	209
Region of Enrollment Units: Subjects			
United States	148	294	442
Taiwan	7	13	20
Slovakia	9	3	12
Greece	2	0	2
Ukraine	12	21	33
Russian Federation	12	21	33
Colombia	13	22	35
Sri Lanka	4	5	9
India	13	7	20
Malaysia	1	3	4
Australia	1	9	10
South Africa	23	59	82
Korea, Republic of	8	9	17
Lithuania	16	15	31
Hungary	4	10	14
Mexico	18	25	43
Argentina	9	14	23
Poland	42	36	78
Brazil	5	4	9

Croatia	1	3	4
Romania	1	2	3
Bulgaria	12	12	24
Germany	2	2	4
Japan	44	72	116
New Zealand	7	11	18
Race Units: Subjects			
American Indian or Alaska Native	17	36	53
Asian	82	125	207
Native Hawaiian or Other Pacific Islander	1	1	2
Black or African American	24	43	67
White	285	450	735
More than one race	5	13	18
Unknown or Not Reported	0	4	4
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	52	100	152
Not Hispanic or Latino	218	365	583
Unknown or Not Reported	144	207	351
Age Continuous Units: Years			
arithmetic mean	52.9	52.4	
standard deviation	± 10.9	± 11.7	-

End points

End points reporting groups

Reporting group title	120 mg LY2127399 (LY A)

Reporting group description:

120 milligrams (mg) LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W).
Participants from Studies BCDO, BCDV and BCDM who were on 120 mg LY2127399 SC Q4W immediately prior to Study H9B-MC-BCDP (BCDP) enrollment remained on 120 mg LY2127399 SC Q4W. Participants from Studies BCDO, BCDV and BCDM who were on placebo immediately prior to Study BCDP enrollment were randomized to receive a loading dose of 240 mg LY2127399 SC, 4 weeks later followed by 120 mg LY2127399 SC Q4W for the subsequent treatment.

Reporting group title	90 mg LY2127399 (LY B)

Reporting group description:

90 mg LY2127399 administered SC every 2 weeks (Q2W).

Participants from Studies BCDO, BCDV and BCDM who were on 90 mg LY2127399 SC Q2W immediately prior to Study BCDP enrollment remained on 90 mg LY2127399 SC Q2W. Participants from Studies BCDO, BCDV and BCDM who were on placebo immediately prior to Study BCDP enrollment were randomized to receive a loading dose of 180 mg LY2127399 SC, 2 weeks later followed by 90 mg LY2127399 SC Q2W for the subsequent treatment.

Subject analysis set title	LY A
Subject analysis set type	Sub-group analysis

Subject analysis set description:

120 mg LY2127399 administered SC Q4W (LY A).
All Week 16 responders from Studies BCDO and BCDV who were randomized to 120 mg LY2127399 SC Q4W at Week 0 of Studies BCDO and BCDV.

Subject analysis set title	LY B
Subject analysis set type	Sub-group analysis

Subject analysis set description:

90 mg LY2127399 administered SC Q2W (LY B).
All Week 16 responders from Studies BCDO and BCDV who were randomized to 90 mg LY2127399 SC Q2W at Week 0 of Studies BCDO and BCDV.

Subject analysis set title	NR LY A to LY B
Subject analysis set type	Sub-group analysis

Subject analysis set description:

90 mg LY2127399 administered SC Q2W.
All Week 16 non-responders (NR) from Studies BCDO and BCDV who were randomized to 120 mg LY2127399 SC Q4W at Week 0 of Studies BCDO and BCDV and assigned to 90 mg LY2127399 SC Q2W at Week 16 of Studies BCDO and BCDV.

Subject analysis set title	NR LY B to LY B
Subject analysis set type	Sub-group analysis

Subject analysis set description:

90 mg LY2127399 administered SC Q2W.
All Week 16 NR from Studies BCDO and BCDV who were randomized to 90 mg LY2127399 SC Q2W at Week 0 of Studies BCDO and BCDV and continued to receive 90 mg LY2127399 SC Q2W at Week 16 of Studies BCDO and BCDV.

Subject analysis set title	NR Placebo to LY B
Subject analysis set type	Sub-group analysis

Subject analysis set description:

90 mg LY2127399 administered SC Q2W.
All Week 16 NR from Studies BCDO and BCDV who were randomized to placebo SC Q2W at Week 0 of Studies BCDO and BCDV and assigned to 90 mg LY2127399 SC Q2W at Week 16 of Studies BCDO and BCDV.

Subject analysis set title	Placebo to LY A

Subject analysis set type	Sub-group analysis

Subject analysis set description:

120 mg LY2127399 administered SC Q4W (240 mg LY2127399 loading dose at Week 0).
All Week 16 responders from Studies BCDO and BCDV who were randomized to placebo SC Q2W at Week 0 of Studies BCDO and BCDV and were randomized to receive 120 mg LY2127399 SC Q4W in Study BCDP.

Subject analysis set title	Placebo to LY B
Subject analysis set type	Sub-group analysis

Subject analysis set description:

90 mg LY2127399 administered SC Q2W (180 mg LY2127399 loading dose at Week 0).
All Week 16 responders from Studies BCDO and BCDV who were randomized to placebo SC Q2W at Week 0 of Studies BCDO and BCDV and were randomized to receive 90 mg LY2127399 SC Q2W in Study BCDP.

Primary: Number of Participants Who Had Treatment-Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs) and Adverse Event of Special Interest (AESI) During Treatment Period

End point title	Number of Participants Who Had Treatment-Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs) and Adverse Event of Special Interest (AESI) During Treatment Period[1]

End point description:

A TEAE was defined as an event that first occurred or worsened in severity on or after the date of the first injection and prior to study termination. AESI are infection, injection site reactions, malignancy, major adverse cardiovascular events (MACE), allergy and hypersensitivity, depression, suicide/self-injury and pregnancy. MACE were defined as 1 of the adjudicated events: cardiovascular death, Myocardial infarction (MI), stroke, hospitalization for unstable angina, hospitalization for heart failure, coronary revascularization procedure, peripheral revascularization procedure, cardiogenic shock due to MI, resuscitated sudden death, serious arrhythmia, hospitalization for hypertension, peripheral arterial event. A summary of SAEs and other non-serious AEs, regardless of causality, is located in the Reported Adverse Events module.

End point type	Primary

End point timeframe:

up to 84.4 weeks during treatment period

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The study was terminated early due to insufficient efficacy; no statistical analyses were conducted.

End point values	120 mg LY2127399 (LY A)	90 mg LY2127399 (LY B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	414	672		
Units: participants				
number (not applicable)				
TEAE	259	422		
SAE	30	57		
Infection	127	266		
Injection Site Reaction	15	30		
Malignancy	0	7		
Major Adverse Cardiovascular Events (MACE)	4	6		
Allergy and Hypersensitivity	13	23		
Depression	7	10		
Suicide/Self-injury	1	0		
Pregnancy	1	2		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Developing Anti-LY2127399 Antibodies

End point title	Percentage of Participants Developing Anti-LY2127399 Antibodies[2]

End point description:

Participants with treatment-emergent anti-LY2127399 antibodies were participants who had any samples from baseline up to and through Week 72 that was a 4-fold increase (2-dilution increase) in immunogenicity titer over baseline titer, or participants who tested negative at baseline and positive post-baseline (at titer of ≥1:20). Baseline is defined as the last non-missing observation on or prior to the date of the first injection of LY2127399 in preceding studies or Study BCDP. Percentage of participants with anti-LY2127399 antibodies=(number of participants with treatment-emergent anti-LY2127399 antibodies / number of participants assessed)*100.

Analysis Population Description: All participants from Studies BCDO and BCDV with an evaluable baseline anti-LY2127399 antibodies result and a post-baseline anti-LY2127399 antibodies result. Participants missing an evaluable baseline result with a negative post-baseline results were included.

End point type	Primary

End point timeframe:

Baseline through Weeks 4, 24, 48 and 72

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The study was terminated early due to insufficient efficacy; no statistical analyses were conducted.

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	291	292	88	88
Units: percentage of participants				
number (not applicable)				
Week 4 (n=291, 292, 88, 88, 67, 97, 102)	1.7	0.3	3.4	1.1
Week 24 (n= 267, 280, 75, 72, 56, 90, 95)	0.7	0.7	1.3	1.4
Week 48 (n= 156, 157, 50, 39, 31, 54, 62)	0	0.6	0	0
Week 72 (n= 61, 68, 27, 17, 16, 22, 22)	0	0	0	0

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	67	97	102	
Units: percentage of participants				

number (not applicable)				
Week 4 (n=291, 292, 88, 88, 67, 97, 102)	1.5	2.1	1	
Week 24 (n= 267, 280, 75, 72, 56, 90, 95)	0	1.1	0	
Week 48 (n= 156, 157, 50, 39, 31, 54, 62)	0	0	0	
Week 72 (n= 61, 68, 27, 17, 16, 22, 22)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Absolute B Cell Counts

End point title	Change from Baseline in Absolute B Cell Counts[3]

End point description:

Cell-surface marker cluster designation (CD) 3 negative, CD20 positive (CD3-CD20+) defines total mature B cells. B-lymphocyte antigen CD20 is an activated-glycosylated phosphoprotein expressed on the surface of all mature B cells. Baseline B cell count is the average of the values on or prior to the date of first injection of study treatment in preceding studies, including unscheduled visits. A positive or negative change indicated an increase or decrease, respectively, in B cell count.

Analysis Population Description: All participants from Studies BCDO and BCDV with an evaluable baseline anti-LY2127399 antibodies result and a post-baseline anti-LY2127399 antibodies result. Participants missing an evaluable baseline result with a negative post-baseline results were included.

End point type	Primary

End point timeframe:

Baseline, Week 48

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The study was terminated early due to insufficient efficacy; no statistical analyses were conducted.

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	302	305	90	88
Units: cells/microliter (cells/µL)				
arithmetic mean (standard deviation)	-111.68 (± 155.59)	-121.3 (± 132.68)	-134.68 (± 130.21)	-110.92 (± 125.3)

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	70	102	105	
Units: cells/microliter (cells/µL)				
arithmetic mean (standard deviation)	-99.67 (± 126.55)	-75.92 (± 126.55)	-104.67 (± 143.24)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Serum Immunoglobulin (Ig) Levels

End point title	Change from Baseline in Serum Immunoglobulin (Ig) Levels[4]

End point description:

Immunoglobulins (Ig), or antibodies, are large proteins used by the immune system to identify and neutralize foreign particles such as bacteria and viruses. Their normal blood levels indicate proper immune status. Change from baseline serum immunoglobulin A (IgA), immunoglobulin G (IgG), and immunoglobulin M (IgM) levels are reported. A negative change indicated a decrease in Ig levels. Baseline is defined as the last non-missing observation on or prior to the date of the first injection of LY2127399 in preceding studies or Study BCDP.

Analysis Population Description: All participants from Studies BCDO and BCDV with an evaluable serum Ig data. LOCF was used to impute missing post-baseline values.

End point type	Primary

End point timeframe:

Baseline, Week 48

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The study was terminated early due to insufficient efficacy; no statistical analyses were conducted.

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	306	307	90	91
Units: grams/liter (g/L)				
arithmetic mean (standard deviation)				
IgA	-0.402 (± 0.58)	-0.424 (± 0.604)	-0.499 (± 0.681)	-0.465 (± 0.501)
IgG	-1.465 (± 2.112)	-1.366 (± 2.166)	-1.321 (± 2.071)	-1.196 (± 2.276)
IgM	-0.346 (± 0.372)	-0.332 (± 0.465)	-0.422 (± 0.505)	-0.387 (± 0.267)

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	71	104	105	
Units: grams/liter (g/L)				
arithmetic mean (standard deviation)				
IgA	-0.298 (± 0.376)	-0.3 (± 0.59)	-0.407 (± 0.481)	
IgG	-1.42 (± 1.651)	-1.376 (± 2.295)	-1.415 (± 2.163)	

IgM	-0.287 (± 0.228)	-0.256 (± 0.289)	-0.267 (± 0.298)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with American College of Rheumatology 20% Response (ACR20)

End point title	Percentage of Participants with American College of Rheumatology 20% Response (ACR20)

End point description:

ACR Responder Index is a Composite of clinical, laboratory, and functional measures of rheumatoid arthritis (RA). ACR20 Responders: had ≥20% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥20% improvement in at least 3 of 5 criteria: participant's and physician's global assessment of disease activity, Health Assessment Questionnaire-Disability Index (HAQ-DI) (which measured participants' perceived degree of difficulty performing daily activities), joint pain, and C-reactive protein (CRP). Baseline is defined as the last non-missing observation on or prior to the date of the first injection of LY2127399 in preceding studies or Study BCDP. Percentage of participants achieving ACR20 response=(number of ACR20 responders / number of participants treated) * 100. All participants who discontinue study treatment for any reason were defined as NR at that time point and going forward.

End point type	Secondary

End point timeframe:

Baseline through Weeks 12, 24 and 48

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	308[5]	308[6]	91[7]	92[8]
Units: percentage of participants				
number (not applicable)				
Week 12	41.9	46.1	30.8	21.7
Week 24	37.3	37	29.7	16.3
Week 48	14	15.9	18.7	7.6

Notes:

[5] - All participants from Studies BCDO and BCDV with evaluable ACR20 responder data.

[6] - All participants from Studies BCDO and BCDV with evaluable ACR20 responder data.

[7] - All participants from Studies BCDO and BCDV with evaluable ACR20 responder data.

[8] - All participants from Studies BCDO and BCDV with evaluable ACR20 responder data.

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	72[9]	105[10]	106[11]	
Units: percentage of participants				
number (not applicable)				
Week 12	25	8.6	4.7	

Week 24	27.8	6.7	9.4	
Week 48	16.7	6.7	5.7	

Notes:

[9] - All participants from Studies BCDO and BCDV with evaluable ACR20 responder data.

[10] - All participants from Studies BCDO and BCDV with evaluable ACR20 responder data.

[11] - All participants from Studies BCDO and BCDV with evaluable ACR20 responder data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Disease Activity Score Based on 28 Joint Count and C-Reactive Protein Level (DAS28-CRP)

End point title	Change from Baseline in Disease Activity Score Based on 28 Joint Count and C-Reactive Protein Level (DAS28-CRP)

End point description:

End point type	Secondary

End point timeframe:

Baseline, 240 weeks

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[12]	0[13]	0[14]	0[15]
Units: NA				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[12] - No participants were analyzed due to early termination of the study.

[13] - No participants were analyzed due to early termination of the study.

[14] - No participants were analyzed due to early termination of the study.

[15] - No participants were analyzed due to early termination of the study.

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[16]	0[17]	0[18]	
Units: NA				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[16] - No participants were analyzed due to early termination of the study.

[17] - No participants were analyzed due to early termination of the study.

[18] - No participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with DAS28-Based European League Against Rheumatism (EULAR-28) Response

End point title	Percentage of Participants with DAS28-Based European League

	Against Rheumatism (EULAR-28) Response

End point description:

End point type	Secondary

End point timeframe:

Baseline through 240 weeks

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[19]	0[20]	0[21]	0[22]
Units: NA				
number (not applicable)				

Notes:

[19] - No participants were analyzed due to early termination of the study.

[20] - No participants were analyzed due to early termination of the study.

[21] - No participants were analyzed due to early termination of the study.

[22] - No participants were analyzed due to early termination of the study.

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[23]	0[24]	0[25]	
Units: NA				
number (not applicable)				

Notes:

[23] - No participants were analyzed due to early termination of the study.

[24] - No participants were analyzed due to early termination of the study.

[25] - No participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Swollen Joint Count (66 joint count)

End point title	Change from Baseline in Swollen Joint Count (66 joint count)

End point description:

End point type	Secondary

End point timeframe:

Baseline, 240 weeks

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[26]	0[27]	0[28]	0[29]
Units: NA				
number (not applicable)				

Notes:

[26] - No participants were analyzed due to early termination of the study.

[27] - No participants were analyzed due to early termination of the study.

[28] - No participants were analyzed due to early termination of the study.

[29] - No participants were analyzed due to early termination of the study.

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[30]	0[31]	0[32]	
Units: NA				
number (not applicable)				

Notes:

[30] - No participants were analyzed due to early termination of the study.

[31] - No participants were analyzed due to early termination of the study.

[32] - No participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey Domain Scores and Summary Scores

End point title	Change from Baseline in Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey Domain Scores and Summary Scores

End point description:

End point type	Secondary

End point timeframe:

Baseline, 240 weeks

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[33]	0[34]	0[35]	0[36]
Units: NA				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[33] - No participants were analyzed due to early termination of the study.

[34] - No participants were analyzed due to early termination of the study.

[35] - No participants were analyzed due to early termination of the study.

[36] - No participants were analyzed due to early termination of the study.

End point values	NR Placebo to	Placebo to LY A	Placebo to LY B	

	LY B			
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[37]	0[38]	0[39]	
Units: NA				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[37] - No participants were analyzed due to early termination of the study.

[38] - No participants were analyzed due to early termination of the study.

[39] - No participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Tender Joint Count (68 Joint Count)

End point title	Change from Baseline in Tender Joint Count (68 Joint Count)

End point description:

End point type	Secondary

End point timeframe:

Baseline, 240 weeks

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[40]	0[41]	0[42]	0[43]
Units: NA				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[40] - No participants were analyzed due to early termination of the study.

[41] - No participants were analyzed due to early termination of the study.

[42] - No participants were analyzed due to early termination of the study.

[43] - No participants were analyzed due to early termination of the study.

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[44]	0[45]	0[46]	
Units: NA				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[44] - No participants were analyzed due to early termination of the study.

[45] - No participants were analyzed due to early termination of the study.

[46] - No participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Participant's Assessment of Pain [Visual Analog

Scale (VAS)]

End point title	Change from Baseline in Participant's Assessment of Pain [Visual Analog Scale (VAS)]

End point description:

End point type	Secondary

End point timeframe:

Baseline, 240 weeks

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[47]	0[48]	0[49]	0[50]
Units: mm				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[47] - No participants were analyzed due to early termination of the study.

[48] - No participants were analyzed due to early termination of the study.

[49] - No participants were analyzed due to early termination of the study.

[50] - No participants were analyzed due to early termination of the study.

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[51]	0[52]	0[53]	
Units: mm				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[51] - No participants were analyzed due to early termination of the study.

[52] - No participants were analyzed due to early termination of the study.

[53] - No participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Participant's Global Assessment of Disease Activity (VAS)

End point title	Change from Baseline in Participant's Global Assessment of Disease Activity (VAS)

End point description:

End point type	Secondary

End point timeframe:

Baseline, 240 weeks

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[54]	0[55]	0[56]	0[57]
Units: Millimeter (mm)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[54] - No participants were analyzed due to early termination of the study.

[55] - No participants were analyzed due to early termination of the study.

[56] - No participants were analyzed due to early termination of the study.

[57] - No participants were analyzed due to early termination of the study.

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[58]	0[59]	0[60]	
Units: Millimeter (mm)				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[58] - No participants were analyzed due to early termination of the study.

[59] - No participants were analyzed due to early termination of the study.

[60] - No participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Physician's Global Assessment of Disease Activity (VAS)

End point title	Change from Baseline in Physician's Global Assessment of Disease Activity (VAS)

End point description:

End point type	Secondary

End point timeframe:

Baseline, 240 weeks

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[61]	0[62]	0[63]	0[64]
Units: mm				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[61] - No participants were analyzed due to early termination of the study.

[62] - No participants were analyzed due to early termination of the study.

[63] - No participants were analyzed due to early termination of the study.

[64] - No participants were analyzed due to early termination of the study.

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[65]	0[66]	0[67]	
Units: mm				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[65] - No participants were analyzed due to early termination of the study.

[66] - No participants were analyzed due to early termination of the study.

[67] - No participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology Percent Improvement (ACR-N)

End point title	American College of Rheumatology Percent Improvement (ACR-N)

End point description:

End point type	Secondary

End point timeframe:

Baseline through 240 weeks

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[68]	0[69]	0[70]	0[71]
Units: NA				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[68] - No participants were analyzed due to early termination of the study.

[69] - No participants were analyzed due to early termination of the study.

[70] - No participants were analyzed due to early termination of the study.

[71] - No participants were analyzed due to early termination of the study.

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[72]	0[73]	0[74]	
Units: NA				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[72] - No participants were analyzed due to early termination of the study.

[73] - No participants were analyzed due to early termination of the study.

[74] - No participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Health Assessment Questionnaire-Disability

Index (HAQ-DI)

End point title	Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI)

End point description:

End point type	Secondary

End point timeframe:

Baseline, 240 weeks

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[75]	0[76]	0[77]	0[78]
Units: NA				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[75] - No participants were analyzed due to early termination of the study.

[76] - No participants were analyzed due to early termination of the study.

[77] - No participants were analyzed due to early termination of the study.

[78] - No participants were analyzed due to early termination of the study..

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[79]	0[80]	0[81]	
Units: NA				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[79] - No participants were analyzed due to early termination of the study.

[80] - No participants were analyzed due to early termination of the study.

[81] - No participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in CRP

End point title	Change from Baseline in CRP

End point description:

End point type	Secondary

End point timeframe:

Baseline, 240 weeks

End point values	LY A	LY B	NR LY A to LY B	NR LY B to LY B
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[82]	0[83]	0[84]	0[85]
Units: NA				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[82] - No participants were analyzed due to early termination of the study.

[83] - No participants were analyzed due to early termination of the study.

[84] - No participants were analyzed due to early termination of the study.

[85] - No participants were analyzed due to early termination of the study.

End point values	NR Placebo to LY B	Placebo to LY A	Placebo to LY B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[86]	0[87]	0[88]	
Units: NA				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[86] - No participants were analyzed due to early termination of the study.

[87] - No participants were analyzed due to early termination of the study.

[88] - No participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Participants Who Died During Treatment Period and Post-Treatment Follow-Up Period

End point title	Number of Participants Who Died During Treatment Period and Post-Treatment Follow-Up Period

End point description:

Analysis Population Description: All enrolled participants.

End point type	Other pre-specified

End point timeframe:

Up to 84.4 weeks during treatment period and discontinuation from study treatment up to 48 weeks during follow-up period

End point values	120 mg LY2127399 (LY A)	90 mg LY2127399 (LY B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	414	672		
Units: participants				
number (not applicable)				
Treatment Period (n=414, 672)	2	4		
Post-Treatment Follow-Up Period (n=368, 591	0	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

H9B-MC-BCDP

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	120 mg LY2127399 (LY A) Treatment Period

Reporting group description:

120 mg LY2127399 administered subcutaneous (SC) every 4 weeks (Q4W).

Participants from Studies BCDO, BCDV and BCDM who were on 120 mg LY2127399 SC Q4W immediately prior to Study BCDP enrollment remained on 120 mg LY2127399 SC Q4W. Participants from Studies BCDO, BCDV and BCDM who were on placebo immediately prior to Study BCDP enrollment were randomized to receive a loading dose of 240 mg LY2127399 SC, 4 weeks later followed by 120 mg LY2127399 SC Q4W for the subsequent treatment.

Reporting group title	90 mg LY2127399 (LY B) Treatment Period

Reporting group description:

90 mg LY2127399 administered SC every 2 weeks (Q2W).

Participants from Studies BCDO, BCDV and BCDM who were on 90 mg LY2127399 SC Q2W immediately prior to Study BCDP enrollment remained on 90 mg LY2127399 SC Q2W. Participants from Studies BCDO, BCDV and BCDM who were on placebo immediately prior to Study BCDP enrollment were randomized to receive a loading dose of 180 mg LY2127399 SC, 2 weeks later followed by 90 mg LY2127399 SC Q2W for the subsequent treatment.

Reporting group title	120 mg LY2127399 (LY A) Follow-Up Period

Reporting group description:

The Post-Treatment Follow-Up Period was defined as the time after study treatment discontinuation visit up to 48 weeks following the last injection of study treatment.

Includes Participants who were previously enrolled in Studies BCDO, BCDV and BCDM and who received 120 mg LY2127399 SC Q4W during Study BCDP treatment period.

Reporting group title	90 mg LY2127399 (LY B) Follow-Up Period

Reporting group description:

The Post-Treatment Follow-Up Period was defined as the time after study treatment discontinuation visit up to 48 weeks following the last injection of study treatment.

Includes Participants who were previously enrolled in Studies BCDO, BCDV and BCDM and who received 90 mg LY2127399 SC Q2W during Study BCDP treatment period.

Serious adverse events	120 mg LY2127399 (LY A) Treatment Period	90 mg LY2127399 (LY B) Treatment Period	120 mg LY2127399 (LY A) Follow-Up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	30 / 414 (7.25%)	57 / 672 (8.48%)	15 / 368 (4.08%)
number of deaths (all causes)	2	4	0
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	2 / 672 (0.30%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervix carcinoma stage 0			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[1]	0 / 339 (0.00%)	1 / 538 (0.19%)	0 / 368 (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
colon adenoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon cancer metastatic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
prostate cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[2]	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
ureteric cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
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 16.0			
subjects affected / exposed[3]	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 301 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
aortic stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
arterial haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
arteriosclerosis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
deep vein thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	1 / 672 (0.15%)	0 / 368 (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
hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[4]	0 / 339 (0.00%)	1 / 538 (0.19%)	0 / 368 (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
pregnancy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[5]	0 / 339 (0.00%)	1 / 538 (0.19%)	0 / 368 (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
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	2 / 672 (0.30%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulcer haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
Reproductive system and breast disorders			
uterine polyp			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[6]	0 / 339 (0.00%)	1 / 538 (0.19%)	0 / 368 (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
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
atelectasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
interstitial lung disease			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
lung infiltration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
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 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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 embolism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	2 / 672 (0.30%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
sleep apnoea syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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			
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
schizoaffective disorder bipolar type			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
Injury, poisoning and procedural complications			
accidental overdose			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
chest injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
fall			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
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 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
fibula fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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 16.0			

subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	2 / 672 (0.30%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pelvic fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal compression fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	1 / 672 (0.15%)	0 / 368 (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
traumatic arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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 limb fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

vascular pseudoaneurysm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	1 / 672 (0.15%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
atrial fibrillation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 414 (0.72%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
cardiac failure congestive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 414 (0.48%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 414 (0.24%)	2 / 672 (0.30%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
left ventricular dysfunction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
palpitations			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
supraventricular tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
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 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar radiculopathy			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
transient ischaemic attack			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertebral artery dissection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
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 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
diabetic retinal oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
diabetic retinopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
maculopathy			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
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 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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 upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon dysplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
duodenal ulcer perforation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
dyspepsia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhoids			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
pancreatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
small intestinal obstruction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	2 / 672 (0.30%)	0 / 368 (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
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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			
cholecystitis chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
cholelithiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic function abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
non-alcoholic steatohepatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
skin ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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			
renal failure acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
Endocrine disorders			

hyperthyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
bunion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bursitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
neuropathic arthropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	2 / 672 (0.30%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteonecrosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 414 (0.48%)	5 / 672 (0.74%)	2 / 368 (0.54%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spondylolisthesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
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 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
bacterial pyelonephritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
bronchiolitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
campylobacter gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis staphylococcal			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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 infective			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
clostridium difficile colitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
diverticulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
infected bunion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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

klebsiella infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
pelvic inflammatory disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[7]	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 301 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumocystis jiroveci pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
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 16.0			
subjects affected / exposed	1 / 414 (0.24%)	1 / 672 (0.15%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 414 (0.48%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
septic shock			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
soft tissue infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subcutaneous abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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

urosepsis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	1 / 672 (0.15%)	0 / 368 (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
wound infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 414 (0.24%)	0 / 672 (0.00%)	0 / 368 (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
diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypercalcaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 414 (0.00%)	0 / 672 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	90 mg LY2127399 (LY B) Follow-Up Period		
Total subjects affected by serious adverse events			
subjects affected / exposed	28 / 591 (4.74%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

basal cell carcinoma				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cervix carcinoma stage 0				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[1]	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
colon adenoma				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
colon cancer metastatic				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
invasive ductal breast carcinoma				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
prostate cancer				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[2]	1 / 118 (0.85%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
squamous cell carcinoma				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
squamous cell carcinoma of skin				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ureteric cancer				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
uterine leiomyoma				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[3]	1 / 473 (0.21%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
aortic stenosis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
arterial haemorrhage				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
arteriosclerosis				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
deep vein thrombosis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypertension				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypotension				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
abortion spontaneous				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[4]	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pregnancy				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[5]	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
chest pain				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
non-cardiac chest pain				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
ulcer haemorrhage				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
uterine polyp				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[6]	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
asthma				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
atelectasis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
interstitial lung disease				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lung infiltration				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
pleural effusion				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pulmonary embolism				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sleep apnoea syndrome				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
depression				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
schizoaffective disorder bipolar type				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
accidental overdose			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
chest injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
fall			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 591 (0.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
femur fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 591 (0.34%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
fibula fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
foot fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
humerus fracture				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
meniscus injury				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pelvic fracture				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
spinal compression fracture				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
traumatic arthritis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
upper limb fracture				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

vascular pseudoaneurysm				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
acute myocardial infarction				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
arteriosclerosis coronary artery				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
atrial fibrillation				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cardiac failure acute				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cardiac failure congestive				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
coronary artery disease				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
left ventricular dysfunction				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
palpitations				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
supraventricular tachycardia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
cerebrovascular accident				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
ischaemic stroke				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lumbar radiculopathy				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
transient ischaemic attack				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
vertebral artery dissection				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
anaemia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
diabetic retinal oedema				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diabetic retinopathy				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
maculopathy				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	1 / 591 (0.17%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
abdominal adhesions			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
colon dysplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
duodenal ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
duodenal ulcer perforation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
dyspepsia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastritis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
haemorrhoids				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
nausea				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pancreatitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
small intestinal obstruction				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
vomiting				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Hepatobiliary disorders			
cholecystitis chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cholelithiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hepatic function abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
non-alcoholic steatohepatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 591 (0.34%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
skin ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
renal failure acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			

hyperthyroidism				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
arthralgia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
arthritis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
back pain				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bunion				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
bursitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
intervertebral disc protrusion				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
neuropathic arthropathy				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
osteoarthritis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	3 / 591 (0.51%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
osteonecrosis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
rheumatoid arthritis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	3 / 591 (0.51%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
spondylolisthesis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
synovial cyst				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 591 (0.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
appendicitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
bacterial pyelonephritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
bronchiolitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
campylobacter gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 591 (0.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
cellulitis staphylococcal			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cholecystitis infective				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
clostridium difficile colitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
diverticulitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastroenteritis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
infected bunion				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
influenza				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

klebsiella infection				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pelvic inflammatory disease				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[7]	1 / 473 (0.21%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
pneumocystis jiroveci pneumonia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pyelonephritis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
sepsis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
septic shock				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	1 / 591 (0.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
soft tissue infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 591 (0.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
staphylococcal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 591 (0.17%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
subcutaneous abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 591 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

urosepsis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
wound infection				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
dehydration				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diabetes mellitus				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 591 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypercalcaemia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 591 (0.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been 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: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been 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: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been 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: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been 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: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been 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: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been 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: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	120 mg LY2127399 (LY A) Treatment Period	90 mg LY2127399 (LY B) Treatment Period	120 mg LY2127399 (LY A) Follow-Up Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	130 / 414 (31.40%)	251 / 672 (37.35%)	47 / 368 (12.77%)
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	11 / 414 (2.66%)	9 / 672 (1.34%)	1 / 368 (0.27%)
occurrences (all)	11	11	1
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 414 (1.45%)	15 / 672 (2.23%)	3 / 368 (0.82%)
occurrences (all)	6	15	3
General disorders and administration site conditions			
injection site reaction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 414 (1.69%)	16 / 672 (2.38%)	0 / 368 (0.00%)
occurrences (all)	10	44	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	10 / 414 (2.42%)	13 / 672 (1.93%)	0 / 368 (0.00%)
occurrences (all)	11	14	0
Musculoskeletal and connective tissue disorders			

arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	16 / 414 (3.86%)	25 / 672 (3.72%)	3 / 368 (0.82%)
occurrences (all)	19	27	3
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	9 / 414 (2.17%)	6 / 672 (0.89%)	2 / 368 (0.54%)
occurrences (all)	9	7	2
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	26 / 414 (6.28%)	59 / 672 (8.78%)	10 / 368 (2.72%)
occurrences (all)	33	65	10
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	15 / 414 (3.62%)	30 / 672 (4.46%)	5 / 368 (1.36%)
occurrences (all)	15	36	7
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 414 (1.45%)	18 / 672 (2.68%)	3 / 368 (0.82%)
occurrences (all)	6	19	3
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	21 / 414 (5.07%)	38 / 672 (5.65%)	12 / 368 (3.26%)
occurrences (all)	32	44	17
sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	17 / 414 (4.11%)	23 / 672 (3.42%)	3 / 368 (0.82%)
occurrences (all)	19	26	3
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	23 / 414 (5.56%)	73 / 672 (10.86%)	8 / 368 (2.17%)
occurrences (all)	36	89	8
urinary tract infection			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	16 / 414 (3.86%)	17 / 672 (2.53%)	2 / 368 (0.54%)
occurrences (all)	19	22	2

Non-serious adverse events	90 mg LY2127399 (LY B) Follow-Up Period		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	71 / 591 (12.01%)		
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 591 (0.51%)		
occurrences (all)	3		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 591 (0.68%)		
occurrences (all)	4		
General disorders and administration site conditions			
injection site reaction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 591 (0.17%)		
occurrences (all)	9		
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 591 (0.17%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 591 (0.34%)		
occurrences (all)	2		
pain in extremity			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 591 (0.34%)		
occurrences (all)	2		
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	15 / 591 (2.54%)		
occurrences (all)	21		
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	13 / 591 (2.20%)		
occurrences (all)	13		
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 591 (0.51%)		
occurrences (all)	3		
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	12 / 591 (2.03%)		
occurrences (all)	14		
sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	11 / 591 (1.86%)		
occurrences (all)	12		
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	11 / 591 (1.86%)		
occurrences (all)	11		
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 591 (0.85%)		
occurrences (all)	7		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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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.

Study BCDP was terminated early due to insufficient efficacy observed in Studies BCDM and BCDV. 4 participants enrolled from Study BCDM were included in TEAE, SAE, AESI and death summary but not in summary of other primary or secondary measures.

Notes: