Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of LY2127399 in Patients with Rheumatoid Arthritis (RA) with or without Background Disease-Modifying Anti-rheumatic Drug (DMARD) Therapy (FLEX O)

Summary

EudraCT number	2010-022206-40
Trial protocol	HU LT BG PL SK
Global end of trial date	26 July 2013

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-BCDO

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01202760
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 12978

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	26 July 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 July 2013
Was the trial ended prematurely?	No

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 in the treatment of rheumatoid arthritis with or without background disease-modifying anti-rheumatic drug (DMARD) therapy.

This study is comprised of 2 periods:

Period 1 - 24-week blinded treatment

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	17 January 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: 334
Country: Number of subjects enrolled	Argentina: 18
Country: Number of subjects enrolled	Colombia: 23
Country: Number of subjects enrolled	Mexico: 60
Country: Number of subjects enrolled	Bulgaria: 38
Country: Number of subjects enrolled	Croatia: 6
Country: Number of subjects enrolled	Hungary: 21
Country: Number of subjects enrolled	Lithuania: 35
Country: Number of subjects enrolled	Poland: 61
Country: Number of subjects enrolled	Romania: 4
Country: Number of subjects enrolled	Russian Federation: 35
Country: Number of subjects enrolled	Slovakia: 13
Country: Number of subjects enrolled	Ukraine: 37

Country: Number of subjects enrolled	Australia: 7
Country: Number of subjects enrolled	India: 32
Country: Number of subjects enrolled	Japan: 114
Country: Number of subjects enrolled	Korea, Republic of: 18
Country: Number of subjects enrolled	Malaysia: 7
Country: Number of subjects enrolled	New Zealand: 14
Country: Number of subjects enrolled	Sri Lanka: 10
Country: Number of subjects enrolled	South Africa: 94
Country: Number of subjects enrolled	Taiwan: 23
Worldwide total number of subjects	1004
EEA total number of subjects	178

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)	894
From 65 to 84 years	110
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

No Text entered.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	120 mg LY2127399

Arm description:

LY2127399: 120 milligrams (mg), subcutaneous (SC) injection, every 4 weeks for 24 weeks. Participants received a 240-mg (2 SC injections of 120 mg each) loading dose of LY2127399 when initiating treatment.

During the Treatment Period, for blinding purposes, participants alternated injections of LY2127399 and injections of Placebo every 2 weeks.

After 16 weeks, non-responders received 90 mg of LY2127399 every 2 weeks for the rest of the 24-week Treatment Period.

Arm type	Experimental
Investigational medicinal product name	LY2127399
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

120 milligrams (mg) LY2127399, subcutaneous (SC) injection, every 4 weeks (Q4W) for 24 weeks. Participants received a 240-mg (2 SC injections of 120 mg each) loading dose of LY2127399 when initiating treatment.

Participants alternated injections of LY2127399 and injections of Placebo every 2 weeks for blinding purposes.

After 16 weeks, non-responders received 90 mg of LY2127399 SC every 2 weeks for the rest of the 24-week Treatment Period.

Arm title	90 mg LY2127399

Arm description:

LY2127399: 90 milligrams (mg), subcutaneous (SC) injection, every 2 weeks for 24 weeks. Participants received a 180-mg (2 SC injections of 90 mg each) loading dose of LY2127399 when initiating treatment.

After 16 weeks, non-responders continued to receive 90 mg of LY2127399 every 2 weeks for the rest of the 24-week Treatment Period.

Arm type	Experimental

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

Dosage and administration details:

90 mg LY2127399 SC injection, every 2 weeks (Q2W) for 24 weeks. Participants received a 180-mg (2 SC injections of 90 mg each) loading dose of LY2127399 when initiating treatment.

After 16 weeks, non-responders continued to receive 90 mg of LY2127399 every 2 weeks for the rest of the 24-week Treatment Period.

Arm title	Placebo

Arm description:

Placebo: subcutaneous (SC) injection, every 2 weeks for 24 weeks. Participants received a loading dose of 2 SC injections of Placebo when initiating treatment.

After 16 weeks, non-responders received 90 milligrams (mg) of LY2127399 every 2 weeks for the rest of the 24-week Treatment Period.

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

Dosage and administration details:

Placebo SC injection Q2W for 24 weeks. Participants received a loading dose of 2 SC injections of Placebo when initiating treatment.

After 16 weeks, non-responders received 90 mg LY2127399 Q2W for the rest of the 24-week Treatment Period.

Number of subjects in period 1	120 mg LY2127399	90 mg LY2127399	Placebo
Started	379	374	251
Received at Least One Dose of Study Drug	379	371	250
Completed	332	322	216
Not completed	47	52	35
Adverse event, serious fatal	2	1	-
Consent withdrawn by subject	17	18	14
Physician decision	-	1	-
Adverse event, non-fatal	11	9	10
Sponsor Decision	4	4	-
Lost to follow-up	-	2	1
Entry Criteria Not Met	-	3	1
Lack of efficacy	6	8	7
Protocol deviation	7	5	2
Parent / Caregiver Decision	-	1	-

Baseline characteristics

Reporting groups

Reporting group title	120 mg LY2127399

Reporting group description:

LY2127399: 120 milligrams (mg), subcutaneous (SC) injection, every 4 weeks for 24 weeks. Participants received a 240-mg (2 SC injections of 120 mg each) loading dose of LY2127399 when initiating treatment.

During the Treatment Period, for blinding purposes, participants alternated injections of LY2127399 and injections of Placebo every 2 weeks.

After 16 weeks, non-responders received 90 mg of LY2127399 every 2 weeks for the rest of the 24-week Treatment Period.

Reporting group title	90 mg LY2127399

Reporting group description:

LY2127399: 90 milligrams (mg), subcutaneous (SC) injection, every 2 weeks for 24 weeks. Participants received a 180-mg (2 SC injections of 90 mg each) loading dose of LY2127399 when initiating treatment.

After 16 weeks, non-responders continued to receive 90 mg of LY2127399 every 2 weeks for the rest of the 24-week Treatment Period.

Reporting group title	Placebo

Reporting group description:

Placebo: subcutaneous (SC) injection, every 2 weeks for 24 weeks. Participants received a loading dose of 2 SC injections of Placebo when initiating treatment.

After 16 weeks, non-responders received 90 milligrams (mg) of LY2127399 every 2 weeks for the rest of the 24-week Treatment Period.

Reporting group values	120 mg LY2127399	90 mg LY2127399	Placebo
Number of subjects	379	374	251
Age categorical Units: Subjects			
Gender, Male/Female Units:			
Female	293	295	209
Male	86	79	42
Region of Enrollment Units: Subjects			
United States	126	125	83
Argentina	7	6	5
Colombia	9	9	5
Mexico	20	25	15
Bulgaria	13	13	12
Croatia	2	1	3
Hungary	3	12	6
Lithuania	14	10	11
Poland	27	22	12
Romania	0	1	3
Russian Federation	14	13	8
Slovakia	8	3	2

Ukraine	16	15	6
Australia	2	3	2
India	14	9	9
Japan	44	42	28
Korea, Republic of	7	6	5
Malaysia	2	4	1
New Zealand	6	2	6
Sri Lanka	4	4	2
South Africa	32	38	24
Taiwan	9	11	3
Ethnicity Units: Subjects			
Hispanic or Latino	38	47	24
Not Hispanic or Latino	193	185	133
Unknown or Not Reported	148	142	94
Race Units: Subjects			
American Indian or Alaska Native	13	21	9
Asian	96	93	59
Native Hawaiian or Other Pacific Islander	1	1	0
Black or African American	12	13	14
White	254	235	162
More than one race	2	9	6
Unknown or Not Reported	1	2	1
Age Continuous Units: years			
arithmetic mean	52.4	50.6	51
standard deviation	± 11.2	± 12.2	± 12
Tender Joint Count (68 Count)			
Tender joint (TJ) count is the number of tender and painful joints determined for each participant by examination of 68 joints. Joints were assessed by pressure and joint manipulation on physical examination. Participants were asked for pain sensations on these manipulations and watched for spontaneous pain reactions. Any positive response on pressure, movement, or both is translated into a single tender-versus-nontender dichotomy.			
Units: joint count			
arithmetic mean	22.8	23.7	22.8
standard deviation	± 15.5	± 17.1	± 15.2
Swollen Joint Count (66 Count)			
Swollen joint (SJ) count is the number of swollen joints determined for each participant by examination of 66 joints. Joints were classified as either swollen or not swollen. Swelling was defined as palpable fluctuating synovitis of the joint.			
Units: joint count			
arithmetic mean	14.8	15.3	14.3
standard deviation	± 11.6	± 11.6	± 10.6

Reporting group values	Total		
Number of subjects	1004		
Age categorical Units: Subjects			

Gender, Male/Female Units:			
Female	797		
Male	207		
Region of Enrollment Units: Subjects			
United States	334		
Argentina	18		
Colombia	23		
Mexico	60		
Bulgaria	38		
Croatia	6		
Hungary	21		
Lithuania	35		
Poland	61		
Romania	4		
Russian Federation	35		
Slovakia	13		
Ukraine	37		
Australia	7		
India	32		
Japan	114		
Korea, Republic of	18		
Malaysia	7		
New Zealand	14		
Sri Lanka	10		
South Africa	94		
Taiwan	23		
Ethnicity Units: Subjects			
Hispanic or Latino	109		
Not Hispanic or Latino	511		
Unknown or Not Reported	384		
Race Units: Subjects			
American Indian or Alaska Native	43		
Asian	248		
Native Hawaiian or Other Pacific Islander	2		
Black or African American	39		
White	651		
More than one race	17		
Unknown or Not Reported	4		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Tender Joint Count (68 Count)			

Tender joint (TJ) count is the number of tender and painful joints determined for each participant by examination of 68 joints. Joints were assessed by pressure and joint manipulation on physical examination. Participants were asked for pain sensations on these manipulations and watched for spontaneous pain reactions. Any positive response on pressure, movement, or both is translated into a single tender-versus-nontender dichotomy.

Units: joint count arithmetic mean standard deviation	- 		
Swollen Joint Count (66 Count)			
Swollen joint (SJ) count is the number of swollen joints determined for each participant by examination of 66 joints. Joints were classified as either swollen or not swollen. Swelling was defined as palpable fluctuating synovitis of the joint.			
Units: joint count arithmetic mean standard deviation	- 		

End points

End points reporting groups

Reporting group title	120 mg LY2127399

Reporting group description:

LY2127399: 120 milligrams (mg), subcutaneous (SC) injection, every 4 weeks for 24 weeks. Participants received a 240-mg (2 SC injections of 120 mg each) loading dose of LY2127399 when initiating treatment.

During the Treatment Period, for blinding purposes, participants alternated injections of LY2127399 and injections of Placebo every 2 weeks.

After 16 weeks, non-responders received 90 mg of LY2127399 every 2 weeks for the rest of the 24-week Treatment Period.

Reporting group title	90 mg LY2127399

Reporting group description:

LY2127399: 90 milligrams (mg), subcutaneous (SC) injection, every 2 weeks for 24 weeks. Participants received a 180-mg (2 SC injections of 90 mg each) loading dose of LY2127399 when initiating treatment.

After 16 weeks, non-responders continued to receive 90 mg of LY2127399 every 2 weeks for the rest of the 24-week Treatment Period.

Reporting group title	Placebo

Reporting group description:

Placebo: subcutaneous (SC) injection, every 2 weeks for 24 weeks. Participants received a loading dose of 2 SC injections of Placebo when initiating treatment.

After 16 weeks, non-responders received 90 milligrams (mg) of LY2127399 every 2 weeks for the rest of the 24-week Treatment Period.

Subject analysis set title	Population Pharmacokinetics (PK)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who received at least 1 dose of LY2127399 with evaluable LY2127399 PK data.

Primary: Percentage of Participants With American College of Rheumatology 20% (ACR20) Response

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

End point description:

ACR20 Responder Index: Composite of clinical, laboratory, and functional measures of rheumatoid arthritis. ACR20 Responder: had >=20% improvement from baseline in 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). Percentage of participants achieving ACR20 response=(number of ACR20 responders/number of participants treated)*100. All non-responders at Week 16 as well as all participants who discontinued study treatment at any time, were defined as non-responders starting at that timepoint and going forward, including Week 24 endpoint.

Analysis Population Description (APD): Participants with at least 5/68 tender (TJ) and 5/66 swollen joints (SJ) at baseline and with evaluable ACR20 data.

End point type	Primary

End point timeframe:

Up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	320	316	213	
Units: percentage of participants				
number (not applicable)	34.4	33.5	31.5	

Statistical analyses

Statistical analysis title	ACR20 Response Wk 24 Endpoint LY A

Statistical analysis description:

Odds ratios, CI and p-value are from a logistic regression model using Wald's test with treatment, region, windowed baseline DAS28-CRP, TNF-IR treatment history (yes, no), and background DMARD (MTX, other conventional DMARD, none) as factors. P-value is from Fisher's exact test when logistic regression sample size requirements are not met.

Comparison groups	120 mg LY2127399 v Placebo
Number of subjects included in analysis	533
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.576
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.7

Statistical analysis title	ACR20 Response Wk 24 Endpoint LY B

Statistical analysis description:

Odds ratios, CI and p-value are from a logistic regression model using Wald's test with treatment, region, windowed baseline DAS28-CRP, TNF-IR treatment history (yes, no), and background DMARD (MTX, other conventional DMARD, none) as factors. P-value is from Fisher's exact test when logistic regression sample size requirements are not met.

Comparison groups	90 mg LY2127399 v Placebo
Number of subjects included in analysis	529
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.724
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.66

Secondary: Percentage of Participants With American College of Rheumatology 50% (ACR50) and 70% (ACR70) Responses

End point title	Percentage of Participants With American College of Rheumatology 50% (ACR50) and 70% (ACR70) Responses

End point description:

ACR Responder Index: Composite of clinical, laboratory, and functional measures of rheumatoid arthritis. ACR50 Responder: had >=50% improvement from baseline in both 68 tender joint (TJ) and 66 swollen joint (SJ) counts and >=50% improvement in at least 3/5 criteria: participant's (Pt's) and physician's global assessment of disease activity, HAQ-DI (measured Pts' perceived degree of difficulty performing daily activities), joint pain, and CRP. Percentage of Pt achieving ACR50 response=(number (No) of ACR50 responders/No of Pts treated)*100. ACR70 Responder: had >=70% improvement from baseline in both TJ and SJ counts and >=70% improvement in at least 3 of same 5 criteria for ACR50. Percentage of Pts achieving ACR70 response=(No of ACR70 responders/No of Pts treated)*100. All non-responders at Week 16 as well as all Pts who discontinued study treatment at any time, for any reason, were defined as non-responders starting at that timepoint and going forward, including Week 24 endpoint.

End point type	Secondary

End point timeframe:

Up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	320[1]	316[2]	213[3]	
Units: percentage of participants				
number (not applicable)				
ACR50	11.6	11.7	12.7	
ACR70	4.7	6.3	4.7	

Notes:

[1] - Participants w/ at least 5/68 TJ and 5/66 SJ at BL and had evaluable ACR50 or ACR70 responder data.

[2] - Participants w/ at least 5/68 TJ and 5/66 SJ at BL and had evaluable ACR50 or ACR70 responder data.

[3] - Participants w/ at least 5/68 TJ and 5/66 SJ at BL and had evaluable ACR50 or ACR70 responder data.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

ACR-N is a continuous measure of clinical, laboratory, and functional outcomes in rheumatoid arthritis that characterizes percentage of improvement in disease activity from baseline based on ACR core set. Percentage of improvement was truncated to range of -100 to 100 to minimize impact of outliers (greater values indicate greater percent improvement). This index was calculated as minimum of a) percentage of improvement in TJ count, b) percentage of improvement in SJ count, or c) third highest percentage of improvement of remaining 5 ACR core criteria: If >=3 components of the 5 ACR core criteria were missing, then c) was set to missing; if any of 3 components a), b), or c) were missing, then ACR-N was set to missing. Least Squares (LS) means were calculated using analysis of covariance

(ANCOVA) with treatment, region, tumor necrosis factor-inadequate responder treatment history, and disease-modifying anti-rheumatic drug (DMARD) background as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	318[4]	314[5]	211[6]	
Units: units on a scale				
least squares mean (standard error)	-11.5 (± 4.6)	-9.5 (± 4.6)	-11.5 (± 5)	

Notes:

[4] - Participants with at least 5/68 TJ and at least 5/66 SJ at baseline and with evaluable ACR-N data.

[5] - Participants with at least 5/68 TJ and at least 5/66 SJ at baseline and with evaluable ACR-N data.

[6] - Participants with at least 5/68 TJ and at least 5/66 SJ at baseline and with evaluable ACR-N data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to 24 Weeks in Swollen Joint Count (66 Joint Count)

End point title	Change From Baseline to 24 Weeks in Swollen Joint Count (66 Joint Count)

End point description:

Swollen joint count is the number of swollen joints determined for each participant by examination of 66 joints. Joints were classified as either swollen or not swollen. Swelling was defined as palpable fluctuating synovitis of the joint. LS means were calculated using ANCOVA with treatment, region, tumor necrosis factor-inadequate responder treatment history, and DMARD background as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with at least 5/68 tender joints and at least 5/66 swollen joints at baseline and with evaluable swollen joint count data. Modified last observation carried forward (mLOCF) was used to impute missing postbaseline values. Data after Week 16 for Week 16 non-responders was not included.

End point type	Secondary

End point timeframe:

Baseline, up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	318	315	211	
Units: joint count				
least squares mean (standard error)	-2.59 (± 0.97)	-3.18 (± 0.99)	-3.59 (± 1.05)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to 24 Weeks in Tender Joint Count (68 Joint Count)

End point title	Change From Baseline to 24 Weeks in Tender Joint Count (68 Joint Count)

End point description:

Tender joint count is the number of tender and painful joints determined for each participant by examination of 68 joints. Joints were assessed by pressure and joint manipulation on physical examination. Participants were asked for pain sensations on these manipulations and watched for spontaneous pain reactions. Any positive response on pressure, movement, or both is translated into a single tender-versus-nontender dichotomy. LS means were calculated using ANCOVA with treatment, region, tumor necrosis factor-inadequate responder treatment history, and DMARD background as fixed factors and baseline as a covariate.

Analysis Population Description (APD): All randomized participants with at least 5/68 tender joints and at least 5/66 swollen joints at baseline and with evaluable tender joint count data. Modified last observation carried forward (mLOCF) was used to impute missing postbaseline values. Data after Week 16 for Week 16 non-responders was not included.

End point type	Secondary

End point timeframe:

Baseline, up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	318	315	211	
Units: joint count				
least squares mean (standard error)	-1.61 (± 1.3)	-1.63 (± 1.31)	-2.11 (± 1.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to 24 Weeks in Participant's Assessment of Pain (Visual Analog Scale)

End point title	Change From Baseline to 24 Weeks in Participant's Assessment of Pain (Visual Analog Scale)

End point description:

Participant's assessment of their current arthritis pain using a visual analog scale (VAS) ranged from 0 millimeters (mm) (no pain) to 100 mm (worst possible pain). A decrease in pain score indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment, region, tumor necrosis factor-inadequate responder treatment history, and DMARD background as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with at least 5/68 tender joints and at least 5/66 swollen joints at baseline and with evaluable participant's assessment of pain data. Modified last observation carried forward (mLOCF) was used to impute missing postbaseline values. Data after Week 16 for Week 16 non-responders was not included.

End point type	Secondary

End point timeframe:

Baseline, up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	313	312	208	
Units: millimeters				
least squares mean (standard error)	-9 (± 2.3)	-9.6 (± 2.4)	-6.9 (± 2.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to 24 Weeks in Participant's Global Assessment of Disease Activity (Visual Analog Scale)

End point title	Change From Baseline to 24 Weeks in Participant's Global Assessment of Disease Activity (Visual Analog Scale)

End point description:

Participant's assessment of their current arthritis disease activity using a visual analog scale (VAS) ranged from 0 millimeters (mm) (no arthritis activity) to 100 mm (extremely active arthritis). A decrease in disease activity score indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment, region, tumor necrosis factor-inadequate responder treatment history, and DMARD background as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with at least 5/68 tender joints and at least 5/66 swollen joints at baseline and with evaluable participant's global assessment of disease activity data. Modified last observation carried forward (mLOCF) was used to impute missing postbaseline values. Data after Week 16 for Week 16 non-responders was not included.

End point type	Secondary

End point timeframe:

Baseline, up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	317	313	211	
Units: millimeters				
least squares mean (standard error)	-10.2 (± 2.3)	-10.2 (± 2.4)	-6.9 (± 2.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to 24 Weeks in Physician’s Global Assessment of

Disease Activity (Visual Analog Scale)

End point title	Change From Baseline to 24 Weeks in Physician’s Global Assessment of Disease Activity (Visual Analog Scale)

End point description:

Physician's assessment of the participant's current arthritis disease activity using a visual analog scale (VAS) ranged from 0 millimeters (mm) (no arthritis activity) to 100 mm (extremely active arthritis). A decrease in disease activity score indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment, region, tumor necrosis factor-inadequate responder treatment history, and DMARD background as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with at least 5/68 tender joints and at least 5/66 swollen joints at baseline and with evaluable physician's global assessment of disease activity data. Modified last observation carried forward (mLOCF) was used to impute missing postbaseline values. Data after Week 16 for Week 16 non-responders was not included.

End point type	Secondary

End point timeframe:

Baseline, up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	308	306	201	
Units: millimeters				
least squares mean (standard error)	-10 (± 2.3)	-12.4 (± 2.4)	-9.7 (± 2.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 24 weeks in Disease Activity Score (Based on 28 Joint Count)-C-Reactive Protein (DAS28-CRP)

End point title	Change from Baseline to 24 weeks in Disease Activity Score (Based on 28 Joint Count)-C-Reactive Protein (DAS28-CRP)

End point description:

Disease Activity Score (DAS) modified to include 28 joint count (DAS28) consisted of composite score of following variables: tender joint count (TJC28), swollen joint count (SJC28), C-reactive protein (CRP) (milligrams per liter), and participant global assessment of disease activity using visual analog scale (VAS) (participant global VAS). DAS28-CRP was calculated using following formula: DAS28-CRP=0.56*square root (sqrt)(TJC28)+0.28*sqrt(SJC28)+0.36*natural log(CRP+1)+0.014*participant global VAS+0.96. Scores ranged 1.0-9.4, where lower scores indicated less disease activity and remission is DAS28-CRP <2.6. A decrease in DAS28-CRP indicated an improvement in participant's condition. LS means were calculated using ANCOVA with treatment, region, tumor necrosis factor-inadequate responder treatment history, and DMARD background as fixed factors and baseline as a covariate.

APD: Participants who did not receive assigned treatment or correct treatment and had evaluable

End point type	Secondary

End point timeframe:

Baseline, up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	376	369	249	
Units: units on a scale				
least squares mean (standard error)	-0.42 (± 0.12)	-0.49 (± 0.12)	-0.41 (± 0.13)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 24 weeks in Health Assessment Questionnaire-Disability Index (HAQ-DI)

End point title	Change from Baseline to 24 weeks in Health Assessment Questionnaire-Disability Index (HAQ-DI)

End point description:

The HAQ-DI questionnaire assesses the participant's self-perception on the degree of difficulty [0 (without any difficulty), 1 (with some difficulty), 2 (with much difficulty), and 3 (unable to do)] when dressing and grooming, arising, eating, walking, hygiene, reaching, gripping, and performing other daily activities. Scores for each functional area, which ranged from 0 (no disability) to 3 (severe disability), were averaged to calculate HAQ-DI. A decrease in HAQ-DI score indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment, region, tumor necrosis factor-inadequate responder treatment history, and DMARD background as fixed factors and baseline as a covariate.

APD: All randomized participants with at least 5/68 tender joints and at least 5/66 swollen joints at baseline and with evaluable HAQ-DI data. Modified LOCF was used to impute missing postbaseline values. Data after Week 16 for Week 16 non-responders was not included.

End point type	Secondary

End point timeframe:

Baseline, up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	317	314	211	
Units: units on a scale				
least squares mean (standard error)	-0.21 (± 0.05)	-0.18 (± 0.05)	-0.15 (± 0.05)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to American College of Rheumatology 20% (ACR20) Response

End point title	Time to American College of Rheumatology 20% (ACR20) Response

End point description:

ACR20 Responder Index: Composite of clinical, laboratory, and functional measures of rheumatoid arthritis. ACR20 Responder: 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). The Kaplan-Meier estimator was used to summarize time to ACR20 response over the Treatment Period (24 weeks). The time to American College of Rheumatology 20% (ACR20) response (in weeks) is calculated as:
(Date of the first postbaseline visit during the Treatment Period meeting ACR20 response criteria – Date of first injection of study treatment + 1) / 7.

APD: Participants w/ at least 5/68 TJ and at least 5/66 SJ at baseline and with evaluable ACR20 response data.

End point type	Secondary

End point timeframe:

Baseline through 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	318	315	210	
Units: weeks				
median (confidence interval 95%)	16.7 (16.1 to 20.1)	16.1 (12.1 to 20.1)	16.4 (15.9 to 23.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Probability of an ACR20 Response by 24 Weeks

End point title	Probability of an ACR20 Response by 24 Weeks

End point description:

ACR20 Responder Index: Composite of clinical, laboratory, and functional measures of rheumatoid arthritis. ACR20 Responder: 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). The Kaplan-Meier estimator was used to summarize time to ACR20 response over the Treatment Period (24 weeks). The time to American College of Rheumatology 20% (ACR20) response (in weeks) is calculated as:
(Date of the first postbaseline visit during the Treatment Period meeting ACR20 response criteria - Date of first injection of study treatment + 1) / 7.

APD: Participants with at least 5/68 TJ and at least 5/66 SJ at baseline and with evaluable ACR20 response data.

End point type	Secondary

End point timeframe:

Baseline through 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	318	315	210	
Units: probability of response				
number (not applicable)	0.612	0.611	0.608	

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants with DAS28-Based European League Against Rheumatism (EULAR) Response

End point description:

EULAR Responder index based on 28 joint count categorizes clinical response based on improvement since baseline in DAS28-CRP. Participants are categorized as EULAR responders or non-responders based on improvement of DAS28-CRP scores from baseline. EULAR28 responder is defined as either DAS28-CRP <=5.1 and DAS28-CRP change <-0.6; or DAS28-CRP >5.1 and DAS28-CRP change <-1.2. EULAR28 responder index is defined as good response: DAS28-CRP <=3.2 and DAS28-CRP change <-1.2; moderate response: DAS28-CRP change <-1.2 except cases defined in good response; or DAS28-CRP <=5.1 and DAS28-CRP change <-0.6 and >-1.2. EULAR Remission is defined as a DAS28-CRP score of <2.6.

Analysis Population Description: Participants with at least 5/68 tender joints and at least 5/66 swollen joints at baseline and with evaluable EULAR response data. Modified last observation carried forward (mLOCF) was used to impute missing postbaseline values. Data after Week 16 for Week 16 non-responders was not included.

End point type	Secondary

End point timeframe:

Up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	318	314	211	
Units: percentage of participants				
number (not applicable)	50.3	49.7	46.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 24 Weeks in Medical Outcomes Study 36-Item Short Form (SF-36) Health Status Survey Domain and Summary Scores

End point title	Change from Baseline to 24 Weeks in Medical Outcomes Study 36-Item Short Form (SF-36) Health Status Survey Domain and Summary Scores

End point description:

The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, and 2 component scores (mental [MCS] and physical health [PCS]). Domain scores calculated by summing each item for each domain and transforming scores into 0-100 scale; higher scores indicated better health status. MCS score consisted of social functioning, vitality, mental health, and role-emotional scales. PCS score consisted of physical functioning, bodily pain, role-physical, and general health scales. LS means were calculated using ANCOVA with treatment, region, tumor necrosis factor-inadequate responder treatment history, and DMARD background as fixed factors and baseline as a covariate.

APD: Participants w/at least 5/68 TJ & 5/66 SJ at BL, w/evaluable SF-36 domain & summary scores.

End point type	Secondary

End point timeframe:

Baseline, up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	311	304	206	
Units: units on a scale				
least squares mean (standard error)				
Physical functioning domain	2.07 (± 0.84)	3.14 (± 0.85)	1.48 (± 0.91)	
Bodily pain domain	1.62 (± 0.82)	2.08 (± 0.83)	1.34 (± 0.89)	
Role limitations due to physical problems domain	1.6 (± 0.83)	2.4 (± 0.84)	1.65 (± 0.91)	
Role limitations due to emotional problems domain	3.3 (± 1.01)	3.23 (± 1.02)	3.11 (± 1.09)	
General health perception domain	1.93 (± 0.76)	1.99 (± 0.77)	1.81 (± 0.82)	
Mental health domain	3.09 (± 0.89)	3 (± 0.9)	2.31 (± 0.97)	
Social function domain	1.17 (± 1)	1.24 (± 1.01)	0.33 (± 1.08)	
Vitality domain	2.85 (± 0.87)	2.58 (± 0.88)	2.22 (± 0.94)	
Physical component summary score	1.19 (± 0.79)	2.1 (± 0.79)	1.14 (± 0.85)	
Mental component summary score	3.18 (± 0.95)	2.68 (± 0.96)	2.54 (± 1.03)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in C-Reactive Protein (CRP) up to Week 24 Endpoint

End point title	Change from Baseline in C-Reactive Protein (CRP) up to Week 24 Endpoint

End point description:

CRP is an indicator of inflammation. A negative change indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment, region, tumor necrosis factor-inadequate responder treatment history, and DMARD background as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with at least 5/68 tender joints and 5/66 swollen joints at baseline and with evaluable CRP data. Modified last observation carried forward (mLOCF) was used to impute missing postbaseline values. Data after Week 16 for Week 16 non-responders was not included.

End point type	Secondary

End point timeframe:

Baseline, up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	318	315	211	
Units: milligrams per liter (mg/L)				
least squares mean (standard error)	2.69 (± 1.42)	1.92 (± 1.44)	1.76 (± 1.54)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 24 weeks in Absolute CD3-CD20+ B-cell Counts

End point title	Change from Baseline to 24 weeks in Absolute CD3-CD20+ B-cell Counts

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 determined by calculating the average of the 2 pretreatment B-cell counts obtained once during Days -28 through -7 and on Day 0. A positive or negative change indicated an increase or decrease, respectively in B-cell count. LS means were calculated using ANCOVA with treatment, region, tumor necrosis factor-inadequate responder treatment history, and DMARD background as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	376[7]	370[8]	248[9]	
Units: cells per microliter				
least squares mean (standard error)	-50.5 (± 19.4)	-74.4 (± 19.3)	-0.7 (± 20.9)	

Notes:

[7] - Participants who received at least 1 dose of study treatment with evaluable absolute B-cell data.

[8] - Participants who received at least 1 dose of study treatment with evaluable absolute B-cell data.

[9] - Participants who received at least 1 dose of study treatment with evaluable absolute B-cell data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 24 Weeks in Serum Immunoglobulin (Ig)

Levels

End point title	Change from Baseline to 24 Weeks in Serum Immunoglobulin (Ig) Levels

End point description:

Immunoglobulins, 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 G (IgG), immunoglobulin A (IgA), and immunoglobulin M (IgM) levels are reported. A negative change indicated a decrease in immunoglobulin levels. LS means were calculated using ANCOVA with treatment, region, tumor necrosis factor-inadequate responder treatment history, and DMARD background as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants who received at least 1 dose of study treatment with evaluable serum immunoglobulin (Ig) data. Modified last observation carried forward (mLOCF) was used to impute missing postbaseline values.

End point type	Secondary

End point timeframe:

Baseline, up to 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	374	369	248	
Units: grams per liter (g/L)				
least squares mean (standard error)				
Immunoglobulin G	-0.813 (± 0.165)	-0.758 (± 0.165)	0.117 (± 0.178)	
Immunoglobulin A	-0.209 (± 0.044)	-0.224 (± 0.044)	0.139 (± 0.047)	
Immunoglobulin M	-0.267 (± 0.026)	-0.275 (± 0.025)	-0.049 (± 0.028)	

Statistical analyses

No statistical analyses for this end point

Secondary: Population Pharmacokinetics (PK)

End point title	Population Pharmacokinetics (PK)

End point description:

Population estimate of constant clearance as determined by population pharmacokinetics (PK) analysis. A 2-compartment model was used in PK modeling.

End point type	Secondary

End point timeframe:

Baseline through 24 weeks

End point values	Population Pharmacokinetics (PK)			
Subject group type	Subject analysis set			
Number of subjects analysed	777[10]			
Units: milliliter per hour (mL/h)				
arithmetic mean (confidence interval 95%)	3.6 (3.44 to 3.78)			

Notes:

[10] - Participants who received at least 1 dose of LY2127399 with evaluable LY2127399 PK data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Developing Anti-LY2127399 Antibodies

End point title	Percentage of Participants Developing Anti-LY2127399 Antibodies

End point description:

LY2127399 anti-drug antibodies (ADA) were assessed at baseline, 1, 4, 16, and 24 weeks. Percentage of participants (Pts) with ADA=(number of Pts with treatment-emergent ADA/number of Pts assessed)*100. Pts with treatment-emergent ADA were Pts who had any sample from baseline up to and through Week 24 that was a 4-fold increase (2-dilution increase) in immunogenicity titer over baseline titer, or Pts who tested negative at baseline and positive post-baseline (at titer of ≥1:20).

End point type	Secondary

End point timeframe:

Baseline through 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	376[11]	370[12]	248[13]	
Units: percentage of participants				
number (not applicable)	2.4	1.9	2.8	

Notes:

[11] - All randomized participants who received at least 1 dose of study treatment.

[12] - All randomized participants who received at least 1 dose of study treatment.

[13] - All randomized participants who received at least 1 dose of study treatment.

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-BCDO	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups	
Reporting group title	120 mg LY2127399, Randomized Treatment Period
Reporting group description: -	
Reporting group title	90 mg LY2127399, Randomized Treatment Period
Reporting group description: -	
Reporting group title	Placebo, Randomized Treatment Period
Reporting group description: -	
Reporting group title	120 mg LY2127399, Rescue Period
Reporting group description: -	
Reporting group title	90 mg LY2127399, Rescue Period
Reporting group description: -	
Reporting group title	Placebo, Rescue Period
Reporting group description: -	
Reporting group title	120 mg LY2127399, Follow-up Period
Reporting group description: -	
Reporting group title	90 mg LY2127399, Follow-up Period
Reporting group description: -	
Reporting group title	Placebo, Follow-up Period
Reporting group description: -	
Reporting group title	120 mg LY2127399 to 90 mg LY2127399(Week 16), Follow-up Period
Reporting group description: -	
Reporting group title	Placebo to 90 mg LY2127399 (Week 16), Follow-up Period
Reporting group description: -	

Serious adverse events	120 mg LY2127399, Randomized Treatment Period	90 mg LY2127399, Randomized Treatment Period	Placebo, Randomized Treatment Period
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 379 (3.69%)	8 / 371 (2.16%)	7 / 250 (2.80%)
number of deaths (all causes)	2	1	0
number of deaths resulting from adverse events	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
colon cancer			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	0 / 250 (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
oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spindle cell sarcoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
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 cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[1]	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
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 15.1			
subjects affected / exposed[2]	1 / 293 (0.34%)	0 / 292 (0.00%)	0 / 208 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	0 / 250 (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
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
cystocele			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[3]	0 / 293 (0.00%)	1 / 292 (0.34%)	0 / 208 (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
dysfunctional uterine bleeding			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[4]	1 / 293 (0.34%)	0 / 292 (0.00%)	0 / 208 (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
postmenopausal haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[5]	0 / 293 (0.00%)	0 / 292 (0.00%)	1 / 208 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
pulmonary oedema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Psychiatric disorders			
intentional self-injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	0 / 250 (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
suicide attempt			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	0 / 250 (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			
compression fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	0 / 250 (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
joint dislocation postoperative			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	0 / 250 (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
ulna fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wrist fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	0 / 250 (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			
atrial fibrillation			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	0 / 250 (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
atrioventricular block complete			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	0 / 250 (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
myocardial infarction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	1 / 371 (0.27%)	0 / 250 (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
pericarditis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	0 / 250 (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
Nervous system disorders			
altered state of consciousness			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	1 / 250 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	0 / 250 (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
dystonia			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral sensorimotor neuropathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
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			
gastric ulcer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	0 / 250 (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
gastric ulcer haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
calculus urinary			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	0 / 250 (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
stress urinary incontinence			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	0 / 250 (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			
juvenile arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	1 / 250 (0.40%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatoid arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 379 (0.53%)	0 / 371 (0.00%)	3 / 250 (1.20%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal osteoarthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	1 / 250 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	0 / 250 (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
device related infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	0 / 250 (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
neutropenic sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
peritonsillar abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	0 / 250 (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
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	0 / 371 (0.00%)	0 / 250 (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

wound sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
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	120 mg LY2127399, Rescue Period	90 mg LY2127399, Rescue Period	Placebo, Rescue Period
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 81 (6.17%)	0 / 72 (0.00%)	0 / 56 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
colon cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spindle cell sarcoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
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 cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[1]	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
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 15.1			

subjects affected / exposed[2]	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
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			
hypertension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
cystocele			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[3]	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dysfunctional uterine bleeding			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[4]	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postmenopausal haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[5]	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
pulmonary oedema			

alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
intentional self-injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
compression fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation postoperative			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulna fracture			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	0 / 56 (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
wrist fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrioventricular block complete			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
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			
altered state of consciousness			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dystonia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral sensorimotor neuropathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	0 / 56 (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
Gastrointestinal disorders			
gastric ulcer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
calculus urinary			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress urinary incontinence			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
juvenile arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	0 / 56 (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
rheumatoid arthritis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal osteoarthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutropenic sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonsillar abscess			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	0 / 56 (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
rectal abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
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	120 mg LY2127399, Follow-up Period	90 mg LY2127399, Follow-up Period	Placebo, Follow-up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 40 (0.00%)	4 / 45 (8.89%)	3 / 37 (8.11%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
colon cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (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
spindle cell sarcoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
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 cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[1]	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[2]	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
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			
hypertension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
cystocele			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed[3]	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dysfunctional uterine bleeding			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[4]	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postmenopausal haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[5]	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
pulmonary oedema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
intentional self-injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
compression fracture			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
joint dislocation postoperative			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulna fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wrist fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrioventricular block complete			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pericarditis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
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			
altered state of consciousness			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dystonia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral sensorimotor neuropathy			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
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			
gastric ulcer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
calculus urinary			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress urinary incontinence			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
juvenile arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatoid arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal osteoarthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutropenic sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonsillar abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	120 mg LY2127399 to 90 mg LY2127399(Week 16), Follow-up	Placebo to 90 mg LY2127399 (Week 16), Follow-up Period	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 7 (14.29%)	2 / 12 (16.67%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
colon cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
spindle cell sarcoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
uterine cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[1]	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
uterine leiomyoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[2]	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

hypertension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
cystocele			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[3]	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dysfunctional uterine bleeding			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[4]	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
postmenopausal haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[5]	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
pulmonary oedema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Psychiatric disorders			
intentional self-injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicide attempt			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
compression fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
joint dislocation postoperative			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
radius fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ulna fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
wrist fracture			

alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrioventricular block complete			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myocardial infarction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pericarditis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
altered state of consciousness			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cerebrovascular accident			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dystonia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral sensorimotor neuropathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
gastric ulcer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric ulcer haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
calculus urinary			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
stress urinary incontinence			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
juvenile arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteoarthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rheumatoid arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal osteoarthritis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
device related infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
neutropenic sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
peritonsillar abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal abscess			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
wound sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: 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.

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

Non-serious adverse events	120 mg LY2127399, Randomized Treatment Period	90 mg LY2127399, Randomized Treatment Period	Placebo, Randomized Treatment Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	174 / 379 (45.91%)	154 / 371 (41.51%)	98 / 250 (39.20%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 379 (1.85%)	8 / 371 (2.16%)	6 / 250 (2.40%)
occurrences (all)	7	8	7

hypertensive crisis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[6]	2 / 293 (0.68%)	0 / 292 (0.00%)	0 / 208 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 379 (1.32%)	5 / 371 (1.35%)	7 / 250 (2.80%)
occurrences (all)	5	5	7
injection site erythema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 379 (1.06%)	10 / 371 (2.70%)	2 / 250 (0.80%)
occurrences (all)	9	27	3
injection site reaction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 379 (2.11%)	11 / 371 (2.96%)	2 / 250 (0.80%)
occurrences (all)	10	34	2
pyrexia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 379 (1.85%)	10 / 371 (2.70%)	5 / 250 (2.00%)
occurrences (all)	7	10	6
Reproductive system and breast disorders			
balanitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[7]	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
vaginal haemorrhage			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed[8]	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[9]	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 379 (1.06%)	5 / 371 (1.35%)	2 / 250 (0.80%)
occurrences (all)	4	6	2
sinus congestion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	1 / 371 (0.27%)	0 / 250 (0.00%)
occurrences (all)	1	1	0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 379 (1.85%)	4 / 371 (1.08%)	2 / 250 (0.80%)
occurrences (all)	7	4	2
insomnia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 379 (1.32%)	10 / 371 (2.70%)	1 / 250 (0.40%)
occurrences (all)	5	10	1
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 379 (1.06%)	3 / 371 (0.81%)	1 / 250 (0.40%)
occurrences (all)	4	4	1
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 379 (0.53%)	2 / 371 (0.54%)	1 / 250 (0.40%)
occurrences (all)	2	3	1
blood potassium decreased			
alternative dictionary used:			

MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
computerised tomogram abnormal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 379 (1.32%)	1 / 371 (0.27%)	0 / 250 (0.00%)
occurrences (all)	5	1	0
vitamin d decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	1 / 250 (0.40%)
occurrences (all)	0	0	1
weight increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	1 / 371 (0.27%)	1 / 250 (0.40%)
occurrences (all)	1	1	1
white blood cell count decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	1 / 250 (0.40%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 379 (1.58%)	4 / 371 (1.08%)	1 / 250 (0.40%)
occurrences (all)	6	6	1
procedural pain			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 379 (0.53%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	2	0	0
Cardiac disorders			

mitral valve prolapse			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
balance disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	12 / 379 (3.17%)	5 / 371 (1.35%)	3 / 250 (1.20%)
occurrences (all)	12	7	3
headache			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	16 / 379 (4.22%)	13 / 371 (3.50%)	6 / 250 (2.40%)
occurrences (all)	17	16	9
hypoaesthesia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 379 (0.79%)	2 / 371 (0.54%)	3 / 250 (1.20%)
occurrences (all)	3	2	4
neuropathy peripheral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	1 / 371 (0.27%)	0 / 250 (0.00%)
occurrences (all)	1	1	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 379 (0.79%)	4 / 371 (1.08%)	1 / 250 (0.40%)
occurrences (all)	3	4	1
iron deficiency anaemia			

alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	0 / 250 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
conjunctivitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 379 (0.53%)	0 / 371 (0.00%)	1 / 250 (0.40%)
occurrences (all)	2	0	1
macular pigmentation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 379 (0.79%)	6 / 371 (1.62%)	2 / 250 (0.80%)
occurrences (all)	3	7	3
constipation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	5 / 371 (1.35%)	1 / 250 (0.40%)
occurrences (all)	0	6	1
dental caries			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 379 (0.53%)	0 / 371 (0.00%)	2 / 250 (0.80%)
occurrences (all)	2	0	2
diarrhoea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 379 (2.11%)	8 / 371 (2.16%)	3 / 250 (1.20%)
occurrences (all)	8	10	4
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 379 (0.53%)	1 / 371 (0.27%)	3 / 250 (1.20%)
occurrences (all)	2	1	3
nausea			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	9 / 379 (2.37%)	8 / 371 (2.16%)	6 / 250 (2.40%)
occurrences (all)	9	10	8
stomatitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 379 (0.79%)	1 / 371 (0.27%)	1 / 250 (0.40%)
occurrences (all)	3	1	1
toothache			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	3 / 371 (0.81%)	1 / 250 (0.40%)
occurrences (all)	1	3	1
vomiting			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 379 (1.06%)	3 / 371 (0.81%)	3 / 250 (1.20%)
occurrences (all)	4	3	3
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
haemorrhage subcutaneous			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
papule			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 379 (0.53%)	4 / 371 (1.08%)	6 / 250 (2.40%)
occurrences (all)	2	4	6
skin exfoliation			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
cystitis noninfective			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
dysuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	1 / 250 (0.40%)
occurrences (all)	0	1	1
haematuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	0 / 250 (0.00%)
occurrences (all)	0	1	0
pollakiuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	0 / 250 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	11 / 379 (2.90%)	6 / 371 (1.62%)	8 / 250 (3.20%)
occurrences (all)	11	6	9
back pain			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	10 / 379 (2.64%)	9 / 371 (2.43%)	3 / 250 (1.20%)
occurrences (all)	11	9	3
bursitis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 379 (0.00%)	3 / 371 (0.81%)	1 / 250 (0.40%)
occurrences (all)	0	3	1
joint swelling			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	2 / 371 (0.54%)	2 / 250 (0.80%)
occurrences (all)	1	2	2
muscle spasms			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 379 (1.06%)	1 / 371 (0.27%)	6 / 250 (2.40%)
occurrences (all)	5	1	6
myalgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 379 (1.06%)	2 / 371 (0.54%)	2 / 250 (0.80%)
occurrences (all)	4	3	2
osteopenia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 379 (0.53%)	1 / 371 (0.27%)	0 / 250 (0.00%)
occurrences (all)	2	1	0
rheumatoid arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	17 / 379 (4.49%)	10 / 371 (2.70%)	13 / 250 (5.20%)
occurrences (all)	17	12	13
synovial cyst			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	1 / 371 (0.27%)	2 / 250 (0.80%)
occurrences (all)	1	1	4
synovitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	14 / 379 (3.69%)	9 / 371 (2.43%)	2 / 250 (0.80%)
occurrences (all)	14	9	2
folliculitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	2 / 371 (0.54%)	0 / 250 (0.00%)
occurrences (all)	0	3	0
gastroenteritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	4 / 371 (1.08%)	4 / 250 (1.60%)
occurrences (all)	1	4	4
gastroenteritis viral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	1 / 250 (0.40%)
occurrences (all)	0	1	1
herpes zoster			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 379 (0.26%)	2 / 371 (0.54%)	2 / 250 (0.80%)
occurrences (all)	1	2	3
nasopharyngitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	17 / 379 (4.49%)	14 / 371 (3.77%)	9 / 250 (3.60%)
occurrences (all)	20	16	10
pharyngitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 379 (1.32%)	2 / 371 (0.54%)	3 / 250 (1.20%)
occurrences (all)	5	2	4
pneumonia mycoplasmal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection viral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	2 / 250 (0.80%)
occurrences (all)	0	0	2

sinusitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 379 (1.58%)	11 / 371 (2.96%)	6 / 250 (2.40%)
occurrences (all)	6	12	6
tuberculosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	0 / 371 (0.00%)	0 / 250 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	12 / 379 (3.17%)	28 / 371 (7.55%)	10 / 250 (4.00%)
occurrences (all)	15	29	12
urinary tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 379 (1.85%)	4 / 371 (1.08%)	6 / 250 (2.40%)
occurrences (all)	8	5	8
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 379 (0.79%)	2 / 371 (0.54%)	0 / 250 (0.00%)
occurrences (all)	3	2	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[10]	0 / 293 (0.00%)	1 / 292 (0.34%)	0 / 208 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
hyperlipidaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 379 (0.00%)	1 / 371 (0.27%)	1 / 250 (0.40%)
occurrences (all)	0	1	1

Non-serious adverse events	120 mg LY2127399, Rescue Period	90 mg LY2127399, Rescue Period	Placebo, Rescue Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 81 (28.40%)	16 / 72 (22.22%)	9 / 56 (16.07%)
Vascular disorders			

hypertension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 72 (1.39%)	0 / 56 (0.00%)
occurrences (all)	0	1	0
hypertensive crisis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[6]	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	2 / 72 (2.78%)	0 / 56 (0.00%)
occurrences (all)	1	4	0
injection site reaction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	1 / 56 (1.79%)
occurrences (all)	5	0	1
pyrexia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
balanitis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed[7]	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
vaginal haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[8]	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[9]	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	1	0	0
sinus congestion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	1 / 56 (1.79%)
occurrences (all)	0	0	1
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 72 (1.39%)	0 / 56 (0.00%)
occurrences (all)	0	1	0
aspartate aminotransferase increased			
alternative dictionary used:			

MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
blood potassium decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
computerised tomogram abnormal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 72 (1.39%)	0 / 56 (0.00%)
occurrences (all)	0	1	0
vitamin d decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 81 (2.47%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	2	0	0
white blood cell count decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	1 / 56 (1.79%)
occurrences (all)	0	0	1
procedural pain			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
mitral valve prolapse			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
balance disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	1	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 81 (2.47%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	2	0	0
neuropathy peripheral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	2 / 81 (2.47%)	2 / 72 (2.78%)	0 / 56 (0.00%)
occurrences (all)	2	2	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
conjunctivitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
macular pigmentation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	1	0	0
constipation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 72 (1.39%)	1 / 56 (1.79%)
occurrences (all)	0	1	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	3 / 72 (4.17%)	1 / 56 (1.79%)
occurrences (all)	1	3	1
stomatitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
haemorrhage subcutaneous			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
papule			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	2 / 81 (2.47%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	2	0	0
skin exfoliation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
cystitis noninfective			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
dysuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	1 / 56 (1.79%)
occurrences (all)	0	0	1
haematuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
pollakiuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	1 / 56 (1.79%)
occurrences (all)	1	0	1
back pain			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	2 / 81 (2.47%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	2	0	0
bursitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
joint swelling			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	1	0	0
muscle spasms			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
osteopenia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	1	0	0
rheumatoid arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	1	0	0
synovial cyst			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
synovitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0

Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	2 / 72 (2.78%)	1 / 56 (1.79%)
occurrences (all)	1	2	1
folliculitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	1 / 72 (1.39%)	0 / 56 (0.00%)
occurrences (all)	0	1	0
gastroenteritis viral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 81 (1.23%)	0 / 72 (0.00%)	1 / 56 (1.79%)
occurrences (all)	1	0	1
pharyngitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
pneumonia mycoplasmal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection viral			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 81 (2.47%)	1 / 72 (1.39%)	1 / 56 (1.79%)
occurrences (all)	2	1	1
tuberculosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 81 (3.70%)	2 / 72 (2.78%)	0 / 56 (0.00%)
occurrences (all)	3	2	0
urinary tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 81 (2.47%)	2 / 72 (2.78%)	2 / 56 (3.57%)
occurrences (all)	2	2	2
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[10]	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
hyperlipidaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 81 (0.00%)	0 / 72 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	120 mg LY2127399, Follow-up Period	90 mg LY2127399, Follow-up Period	Placebo, Follow-up Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 40 (30.00%)	17 / 45 (37.78%)	13 / 37 (35.14%)

Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	2 / 37 (5.41%)
occurrences (all)	1	0	2
hypertensive crisis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[6]	1 / 31 (3.23%)	0 / 35 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
injection site erythema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
balanitis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed[7]	0 / 9 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
vaginal haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[8]	1 / 31 (3.23%)	0 / 35 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[9]	0 / 31 (0.00%)	1 / 35 (2.86%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
sinus congestion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
insomnia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	2 / 45 (4.44%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
aspartate aminotransferase increased			
alternative dictionary used:			

MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
blood potassium decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
computerised tomogram abnormal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
liver function test abnormal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
vitamin d decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
weight increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
white blood cell count decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
procedural pain			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
mitral valve prolapse			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Nervous system disorders			
balance disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
dizziness			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
neuropathy peripheral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
sciatica			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Eye disorders			
conjunctivitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
macular pigmentation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
constipation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
dental caries			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
diarrhoea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
nausea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
stomatitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	2
toothache			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
vomiting			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
haemorrhage subcutaneous			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
papule			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
rash			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
skin exfoliation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
skin ulcer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
cystitis noninfective			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
dysuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
haematuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
pollakiuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
back pain			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
bursitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
joint swelling			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
muscle spasms			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
osteopenia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
rheumatoid arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
synovial cyst			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
synovitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	2	0

Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
folliculitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
gastroenteritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
gastroenteritis viral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
herpes zoster			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
pharyngitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
pneumonia mycoplasmal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
respiratory tract infection viral			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
sinusitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	0 / 45 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
tuberculosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 40 (2.50%)	3 / 45 (6.67%)	1 / 37 (2.70%)
occurrences (all)	1	4	1
urinary tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[10]	0 / 31 (0.00%)	0 / 35 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
hyperlipidaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 40 (0.00%)	1 / 45 (2.22%)	0 / 37 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	120 mg LY2127399 to 90 mg LY2127399(Week 16), Follow-up	Placebo to 90 mg LY2127399 (Week 16), Follow-up Period	
Total subjects affected by non-serious adverse events			

subjects affected / exposed	5 / 7 (71.43%)	2 / 12 (16.67%)	
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
hypertensive crisis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[6]	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
injection site erythema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
injection site reaction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
pyrexia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			

balanitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[7]	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
vaginal haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[8]	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
vulvovaginal pruritus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[9]	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
sinus congestion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
insomnia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

aspartate aminotransferase increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
blood potassium decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
computerised tomogram abnormal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
liver function test abnormal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
vitamin d decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
weight increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
white blood cell count decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
procedural pain			

alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Cardiac disorders			
mitral valve prolapse			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
balance disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
dizziness			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
headache			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
hypoaesthesia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
neuropathy peripheral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
sciatica			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			

anaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
iron deficiency anaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
conjunctivitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
macular pigmentation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
constipation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
dental caries			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
diarrhoea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
gastrooesophageal reflux disease			

alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
nausea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
stomatitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
toothache			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
vomiting			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
haemorrhage subcutaneous			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
papule			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
rash			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
skin exfoliation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
skin ulcer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
cystitis noninfective			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
dysuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
haematuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
pollakiuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
back pain			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)		
occurrences (all)	0	0		
bursitis				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)		
occurrences (all)	0	0		
joint swelling				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)		
occurrences (all)	0	0		
muscle spasms				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)		
occurrences (all)	2	0		
myalgia				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)		
occurrences (all)	0	0		
osteopenia				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)		
occurrences (all)	0	0		
rheumatoid arthritis				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)		
occurrences (all)	1	1		
synovial cyst				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)		
occurrences (all)	0	0		
synovitis				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)		
occurrences (all)	0	0		

Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
folliculitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
gastroenteritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
gastroenteritis viral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
herpes zoster			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
nasopharyngitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
pharyngitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
pneumonia mycoplasmal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
respiratory tract infection viral			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
sinusitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
tuberculosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
urinary tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 7 (14.29%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed[10]	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
hyperlipidaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

Notes:

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 May 2011	Amendment A: Added Columbia-Suicide Severity Rating Scale (C-SSRS) for prospective assessment of the occurrence of treatment-emergent suicidality. Modified existing exclusion criteria. Concomitant Medications were updated. Statistical Methodology changes included: o Correcting the significance level for interaction effects from 0.010 to 0.10. o Modification of the text for non-responder imputation for clinical response (ACR20/50/70).
21 June 2011	Amendment B: Correction of the definition of B cell recovery.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported