



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 $\geq 20\%$ improvement from baseline in 68 tender and 66 swollen joint counts and $\geq 20\%$ 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 = $(\text{number of ACR20 responders} / \text{number of participants treated}) \times 100$. 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 $\geq 50\%$ improvement from baseline in both 68 tender joint (TJ) and 66 swollen joint (SJ) counts and $\geq 50\%$ 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 $\geq 70\%$ improvement from baseline in both TJ and SJ counts and $\geq 70\%$ 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 (\pm 2.3) | -12.4 (\pm 2.4) | -9.7 (\pm 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: $\text{DAS28-CRP} = 0.56 \times \sqrt{\text{TJC28}} + 0.28 \times \sqrt{\text{SJC28}} + 0.36 \times \ln(\text{CRP} + 1) + 0.014 \times \text{participant global VAS} + 0.96$. Scores ranged 1.0-9.4, where lower scores indicated less disease activity and remission is $\text{DAS28-CRP} < 2.6$. 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 $\geq 20\%$ 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 $\geq 20\%$ improvement from baseline in both 68 tender and 66 swollen joint counts and $\geq 20\%$ 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 $\geq 1:20$).

| | |
|----------------|-----------|
| 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 |
| gastroesophageal 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 occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 7 (0.00%) 0 / 0 0 / 0 | 0 / 12 (0.00%) 0 / 0 0 / 0 | |
| Immune system disorders anaphylactic reaction alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 7 (0.00%) 0 / 0 0 / 0 | 0 / 12 (0.00%) 0 / 0 0 / 0 | |
| Reproductive system and breast disorders cystocele alternative dictionary used: MedDRA 15.1 subjects affected / exposed ^[3] occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 7 (0.00%) 0 / 0 0 / 0 | 0 / 12 (0.00%) 0 / 0 0 / 0 | |
| dysfunctional uterine bleeding alternative dictionary used: MedDRA 15.1 subjects affected / exposed ^[4] occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 7 (0.00%) 0 / 0 0 / 0 | 0 / 12 (0.00%) 0 / 0 0 / 0 | |
| postmenopausal haemorrhage alternative dictionary used: MedDRA 15.1 subjects affected / exposed ^[5] occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 7 (0.00%) 0 / 0 0 / 0 | 0 / 12 (0.00%) 0 / 0 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders pulmonary oedema alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 7 (0.00%) 0 / 0 0 / 0 | 0 / 12 (0.00%) 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 occurrences (all) | 0 / 379 (0.00%) 0 | 0 / 371 (0.00%) 0 | 0 / 250 (0.00%) 0 |
| Pregnancy, puerperium and perinatal conditions pregnancy alternative dictionary used: MedDRA 15.1 subjects affected / exposed ^[6] occurrences (all) | 2 / 293 (0.68%) 2 | 0 / 292 (0.00%) 0 | 0 / 208 (0.00%) 0 |
| General disorders and administration site conditions fatigue alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) injection site erythema alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) injection site reaction alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) pyrexia alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 5 / 379 (1.32%) 5 4 / 379 (1.06%) 9 8 / 379 (2.11%) 10 7 / 379 (1.85%) 7 | 5 / 371 (1.35%) 5 10 / 371 (2.70%) 27 11 / 371 (2.96%) 34 10 / 371 (2.70%) 10 | 7 / 250 (2.80%) 7 2 / 250 (0.80%) 3 2 / 250 (0.80%) 2 5 / 250 (2.00%) 6 |
| Reproductive system and breast disorders balanitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed ^[7] occurrences (all) vaginal haemorrhage alternative dictionary used: MedDRA 15.1 | 0 / 379 (0.00%) 0 | 0 / 371 (0.00%) 0 | 0 / 250 (0.00%) 0 |

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

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

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

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

| | | | |
|--|------------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 379 (0.00%) 0 | 0 / 371 (0.00%) 0 | 0 / 250 (0.00%) 0 |
| skin ulcer alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 379 (0.00%) 0 | 0 / 371 (0.00%) 0 | 0 / 250 (0.00%) 0 |
| Renal and urinary disorders cystitis noninfective alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 379 (0.00%) 0 | 0 / 371 (0.00%) 0 | 0 / 250 (0.00%) 0 |
| dysuria alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 379 (0.00%) 0 | 1 / 371 (0.27%) 1 | 1 / 250 (0.40%) 1 |
| haematuria alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 379 (0.00%) 0 | 1 / 371 (0.27%) 1 | 0 / 250 (0.00%) 0 |
| pollakiuria alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 379 (0.00%) 0 | 1 / 371 (0.27%) 1 | 0 / 250 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 11 / 379 (2.90%) 11 | 6 / 371 (1.62%) 6 | 8 / 250 (3.20%) 9 |
| back pain alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 10 / 379 (2.64%) 11 | 9 / 371 (2.43%) 9 | 3 / 250 (1.20%) 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 occurrences (all) | 6 / 379 (1.58%) 6 | 11 / 371 (2.96%) 12 | 6 / 250 (2.40%) 6 |
| tuberculosis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 379 (0.00%) 0 | 0 / 371 (0.00%) 0 | 0 / 250 (0.00%) 0 |
| upper respiratory tract infection alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 12 / 379 (3.17%) 15 | 28 / 371 (7.55%) 29 | 10 / 250 (4.00%) 12 |
| urinary tract infection alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 7 / 379 (1.85%) 8 | 4 / 371 (1.08%) 5 | 6 / 250 (2.40%) 8 |
| viral upper respiratory tract infection alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 3 / 379 (0.79%) 3 | 2 / 371 (0.54%) 2 | 0 / 250 (0.00%) 0 |
| vulvovaginal mycotic infection alternative dictionary used: MedDRA 15.1 subjects affected / exposed ^[10] occurrences (all) | 0 / 293 (0.00%) 0 | 1 / 292 (0.34%) 1 | 0 / 208 (0.00%) 0 |
| Metabolism and nutrition disorders hyperlipidaemia alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 379 (0.00%) 0 | 1 / 371 (0.27%) 1 | 1 / 250 (0.40%) 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 occurrences (all) | 0 / 81 (0.00%) 0 | 1 / 72 (1.39%) 1 | 0 / 56 (0.00%) 0 |
| hypertensive crisis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 81 (0.00%) 0 | 0 / 72 (0.00%) 0 | 0 / 56 (0.00%) 0 |
| Pregnancy, puerperium and perinatal conditions pregnancy alternative dictionary used: MedDRA 15.1 subjects affected / exposed ^[6] occurrences (all) | 0 / 81 (0.00%) 0 | 0 / 72 (0.00%) 0 | 0 / 56 (0.00%) 0 |
| General disorders and administration site conditions fatigue alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 81 (0.00%) 0 | 0 / 72 (0.00%) 0 | 0 / 56 (0.00%) 0 |
| injection site erythema alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 1 / 81 (1.23%) 1 | 2 / 72 (2.78%) 4 | 0 / 56 (0.00%) 0 |
| injection site reaction alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 1 / 81 (1.23%) 5 | 0 / 72 (0.00%) 0 | 1 / 56 (1.79%) 1 |
| pyrexia alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 81 (0.00%) 0 | 0 / 72 (0.00%) 0 | 0 / 56 (0.00%) 0 |
| Reproductive system and breast disorders balanitis alternative dictionary used: MedDRA 15.1 | | | |

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

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

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

| | | | |
|---|----------------|----------------|----------------|
| 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 occurrences (all) | 1 / 81 (1.23%) 1 | 2 / 72 (2.78%) 2 | 1 / 56 (1.79%) 1 |
| folliculitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 81 (0.00%) 0 | 0 / 72 (0.00%) 0 | 0 / 56 (0.00%) 0 |
| gastroenteritis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 81 (0.00%) 0 | 1 / 72 (1.39%) 1 | 0 / 56 (0.00%) 0 |
| gastroenteritis viral alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 81 (0.00%) 0 | 0 / 72 (0.00%) 0 | 0 / 56 (0.00%) 0 |
| herpes zoster alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 81 (0.00%) 0 | 0 / 72 (0.00%) 0 | 0 / 56 (0.00%) 0 |
| nasopharyngitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 1 / 81 (1.23%) 1 | 0 / 72 (0.00%) 0 | 1 / 56 (1.79%) 1 |
| pharyngitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 81 (0.00%) 0 | 0 / 72 (0.00%) 0 | 0 / 56 (0.00%) 0 |
| pneumonia mycoplasmal alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 81 (0.00%) 0 | 0 / 72 (0.00%) 0 | 0 / 56 (0.00%) 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 occurrences (all) hypertensive crisis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 0 / 40 (0.00%) 0 | 0 / 45 (0.00%) 0 1 / 45 (2.22%) 1 | 2 / 37 (5.41%) 2 0 / 37 (0.00%) 0 |
| Pregnancy, puerperium and perinatal conditions pregnancy alternative dictionary used: MedDRA 15.1 subjects affected / exposed ^[6] occurrences (all) | 1 / 31 (3.23%) 1 | 0 / 35 (0.00%) 0 | 0 / 27 (0.00%) 0 |
| General disorders and administration site conditions fatigue alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) injection site erythema alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) injection site reaction alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) pyrexia alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 0 / 40 (0.00%) 0 0 / 40 (0.00%) 0 0 / 40 (0.00%) 0 | 0 / 45 (0.00%) 0 0 / 45 (0.00%) 0 0 / 45 (0.00%) 0 0 / 45 (0.00%) 0 | 0 / 37 (0.00%) 0 0 / 37 (0.00%) 0 0 / 37 (0.00%) 0 0 / 37 (0.00%) 0 |
| Reproductive system and breast disorders balanitis alternative dictionary used: MedDRA 15.1 | | | |

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

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

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

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

| | | | |
|---|----------------|----------------|----------------|
| 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 occurrences (all) | 1 / 40 (2.50%) 1 | 0 / 45 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| folliculitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 45 (0.00%) 0 | 1 / 37 (2.70%) 1 |
| gastroenteritis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 1 / 45 (2.22%) 1 | 0 / 37 (0.00%) 0 |
| gastroenteritis viral alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 45 (0.00%) 0 | 1 / 37 (2.70%) 1 |
| herpes zoster alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 45 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| nasopharyngitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 45 (0.00%) 0 | 2 / 37 (5.41%) 2 |
| pharyngitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 0 / 45 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| pneumonia mycoplasmal alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 45 (0.00%) 0 | 1 / 37 (2.70%) 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 occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| hypertensive crisis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Pregnancy, puerperium and perinatal conditions pregnancy alternative dictionary used: MedDRA 15.1 subjects affected / exposed ^[6] occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| General disorders and administration site conditions fatigue alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| injection site erythema alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| injection site reaction alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| pyrexia alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Reproductive system and breast disorders | | | |

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

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

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

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

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

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

| | | |
|---|----------------|----------------|
| 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 occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| folliculitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| gastroenteritis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| gastroenteritis viral alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| herpes zoster alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 12 (0.00%) 0 | |
| nasopharyngitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| pharyngitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| pneumonia mycoplasmal alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 0 / 12 (0.00%) 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