



Clinical trial results:

A Phase 3, Multicenter, Randomized, Double Blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Subcutaneous LY2127399 in Participants with Systemic Lupus Erythematosus (SLE)

Summary

EudraCT number	2010-022099-29
Trial protocol	DE AT IT BG
Global end of trial date	22 June 2015

Results information

Result version number	v1 (current)
This version publication date	27 May 2018
First version publication date	27 May 2018

Trial information

Trial identification

Sponsor protocol code	H9B-MC-BCDS
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01196091
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 13656

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	22 June 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 June 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this SLE study is to evaluate the efficacy, safety and tolerability of two different doses of LY2127399 administered in participants with active SLE.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 November 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Colombia: 44
Country: Number of subjects enrolled	Argentina: 66
Country: Number of subjects enrolled	Puerto Rico: 21
Country: Number of subjects enrolled	Singapore: 2
Country: Number of subjects enrolled	United States: 379
Country: Number of subjects enrolled	Philippines: 86
Country: Number of subjects enrolled	Japan: 45
Country: Number of subjects enrolled	Egypt: 59
Country: Number of subjects enrolled	Ukraine: 74
Country: Number of subjects enrolled	Thailand: 34
Country: Number of subjects enrolled	Belarus: 12
Country: Number of subjects enrolled	Canada: 4
Country: Number of subjects enrolled	Austria: 7
Country: Number of subjects enrolled	Macedonia, the former Yugoslav Republic of: 12
Country: Number of subjects enrolled	Poland: 54
Country: Number of subjects enrolled	Guatemala: 43
Country: Number of subjects enrolled	Korea, Republic of: 43
Country: Number of subjects enrolled	Italy: 10
Country: Number of subjects enrolled	Bulgaria: 31
Country: Number of subjects enrolled	Chile: 13

Country: Number of subjects enrolled	Peru: 99
Country: Number of subjects enrolled	Germany: 24
Country: Number of subjects enrolled	Croatia: 2
Worldwide total number of subjects	1164
EEA total number of subjects	128

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)	1137
From 65 to 84 years	26
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Two sites' participants were excluded due to good clinical practice (GCP) issues. Excluded sites had 5, 11 and 8 participants in LY2127399 Every 2 weeks, LY2127399 Every 4 weeks and Placebo, respectively. No baseline characteristic data is provided.

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

Arms

Are arms mutually exclusive?	Yes
Arm title	LY2127399 every 2 weeks

Arm description:

LY2127399: 120 mg administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.

Arm type	Experimental
Investigational medicinal product name	LY2127399 every 2 weeks
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

120 mg administered via subcutaneous (SC) injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.

Arm title	LY2127399 every 4 wks
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Arm description:

During the Treatment Period, for blinding purposes, patients will alternate injections of LY2127399 and injections of placebo every 2 weeks.

LY2127399: 120 mg administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.

Placebo every 4 weeks: Administered via subcutaneous injection for 52 weeks.

Arm type	Experimental
Investigational medicinal product name	LY2127399 every 4 wks
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

120 mg administered via subcutaneous (SC) injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.

Arm title	Placebo
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Arm description:

Placebo every 2 weeks: Administered via subcutaneous injection for 52 weeks. A matching loading dose will also be administered at the first dose

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

Dosage and administration details:

Administered via subcutaneous injection for 52 weeks. A matching loading dose of corticosteroids, NSAIDs, antimalarials, or immunosuppressants will also be administered at the first dose

Number of subjects in period 1	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo
Started	387	389	388
Received at least 1 Dose of Study Drug	381	378	387
Follow-Up	103 ^[1]	105 ^[2]	128 ^[3]
Completed	299	291	284
Not completed	88	98	104
Adverse event, serious fatal	3	2	2
Parent/Caregiver Decision	-	-	1
Consent withdrawn by subject	16	19	22
Physician decision	3	3	4
Adverse event, non-fatal	22	27	26
Excluded site	5	11	8
Sponsor Decision	6	5	4
Lost to follow-up	5	5	6
Entry Criteria Not Met	11	11	10
Lack of efficacy	15	12	17
Protocol deviation	1	3	3
Randomized, No Study Drug Received	1	-	1

Notes:

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

Justification: Two sites and participants were excluded due to Good Clinical Practice (GCP) issues.

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

Justification: Two sites and participants were excluded due to Good Clinical Practice (GCP) issues.

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

completed, minus those who left.

Justification: Two sites and participants were excluded due to Good Clinical Practice (GCP) issues.

Baseline characteristics

Reporting groups

Reporting group title	LY2127399 every 2 weeks
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Reporting group description:

LY2127399: 120 mg administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.

Reporting group title	LY2127399 every 4 wks
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Reporting group description:

During the Treatment Period, for blinding purposes, patients will alternate injections of LY2127399 and injections of placebo every 2 weeks.

LY2127399: 120 mg administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.

Placebo every 4 weeks: Administered via subcutaneous injection for 52 weeks.

Reporting group title	Placebo
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Reporting group description:

Placebo every 2 weeks: Administered via subcutaneous injection for 52 weeks. A matching loading dose will also be administered at the first dose

Reporting group values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo
Number of subjects	387	389	388
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean	39.8	40.2	39.1
standard deviation	± 12.51	± 11.21	± 11.69
Gender, Male/Female Units: Participants			
Female	354	352	360
Male	27	26	19
Unknown	6	11	9
Ethnicity (NIH/OMB)			
Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP) issues			
Units: Subjects			
Hispanic or Latino	119	116	122
Not Hispanic or Latino	233	225	229

Unknown or Not Reported	35	48	37
Race (NIH/OMB)			
Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP) issues			
Units: Subjects			
American Indian or Alaska Native	65	55	67
Asian	68	61	66
Native Hawaiian or Other Pacific Islander	0	1	0
Black or African American	40	41	39
White	204	218	205
More than one race	4	2	2
Unknown or Not Reported	6	11	9
Region of Enrollment			
Units: Subjects			
Colombia	16	10	18
Argentina	20	24	22
Puerto Rico	3	7	11
Singapore	0	2	0
United States	128	133	116
Philippines	26	14	22
Japan	15	15	15
Egypt	19	19	21
Ukraine	23	22	29
Thailand	14	9	11
Belarus	4	6	2
Canada	2	0	2
Austria	3	3	1
Macedonia, The Former Yugoslav Republic of	3	6	3
Poland	19	16	19
Guatemala	13	17	13
Korea, Republic of	11	18	14
Italy	1	7	2
Bulgaria	8	11	12
Chile	8	0	5
Peru	32	33	34
Germany	12	5	7
Croatia	1	1	0
Unknown	6	11	9
At Least One BILAG A or Two BILAG B Disease Activity Scores			
The British Isles Lupus Assessment Group (BILAG) instrument assesses global disease activity across 9 organ system domains and assessed for each of the 9 organ domains using BILAG2004 index flare rules; A is a severe flare and B is a moderate flare. The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group because not all participants will have at least one BILAG A or Two BILAG B Disease Activity scores.			
Units: Subjects			
Yes	360	340	347
No	21	38	31
Unknown	6	11	10

Anti-dsDNA Antibody Level			
Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP) issues			
Units: International Units/Milliliter (IU/mL)			
arithmetic mean	107.2	110.4	107.1
standard deviation	± 113.50	± 111.58	± 112.40
Safety of Estrogens in Lupus Erythematosus National Assessment (SELENA-SLEDAI) Score			
SELENA SLEDAI is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105; scores > 20 are rare. PGA is a visual analog scale scored from 0 to 3 (0=none, 1=mild, 2=moderate, 3=severe). Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP) issues			
Units: units on a scale			
arithmetic mean	10.2	10.4	10.7
standard deviation	± 3.5	± 3.6	± 3.9
Physician's Global Assessment (PGA) Score			
PGA is a single-item clinician rated assessment of the participant's current level of disease activity measured on a continuous 100-millimeter (mm) visual analytic scale with benchmarks of 0, 1, 2, and 3 from left to right corresponding to no, mild, moderate, and severe SLE disease activity. Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP).			
Units: units on a scale			
arithmetic mean	46.3	46.1	47.1
standard deviation	± 15.7	± 16.2	± 16.10
Time of Onset of Lupus			
Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP) issues			
Units: years			
arithmetic mean	7.5	8.1	6.4
standard deviation	± 7.4	± 7.9	± 6.8
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Physical Health			
34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) with SLE within 8 domains: physical health (8 items), emotional health (6 items), body image (5 items), pain (3 items), planning (3 items), fatigue (4 items), intimate relationships (2 items), and burden to others (3 items). Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites which were excluded due to suspected GCP practices.			
Units: units on a scale (transformed)			
arithmetic mean	59.2	59.1	56.9
standard deviation	± 24.98	± 25.13	± 26.17
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Emotional Health			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationships (2 items), and burden to others (3 items). Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed)			
arithmetic mean	65.7	66.7	64.6
standard deviation	± 25.19	± 23.99	± 26.22

Lupus Quality of Life (lupus QOL) Composite and Domain Scores Body Image			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health (8 items), emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed)			
arithmetic mean	61.1	63.2	61.9
standard deviation	± 28.99	± 27.67	± 29.20
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Pain			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed)			
arithmetic mean	56.1	56.9	53.6
standard deviation	± 28.40	± 26.75	± 28.62
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Planning			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed)			
arithmetic mean	61.2	62.1	59.0
standard deviation	± 30.37	± 28.69	± 30.92
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Fatigue			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed)			
arithmetic mean	56.0	54.4	53.4
standard deviation	± 26.39	± 25.54	± 27.14
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Intimate Relationships			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed)			
arithmetic mean	56.2	63.3	56.8
standard deviation	± 33.92	± 31.53	± 34.21
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Burden to Others			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			

Units: units on a scale (transformed)			
arithmetic mean	52.8	51.9	49.3
standard deviation	± 30.70	± 30.31	± 32.39
Brief Fatigue Inventory (BFI) Score (Worst Level of Fatigue in the Last 24 Hours)			
BFI is a participants-reported scale that measures the severity of fatigue based on the worst fatigue experienced during the past 24-hours. The severity scores ranged from 0 (no fatigue) to 10 (fatigue as severe as you can imagine). Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP) issues.			
Units: units on a scale			
arithmetic mean	5.8	5.6	5.6
standard deviation	± 2.57	± 2.81	± 2.81

Reporting group values	Total		
Number of subjects	1164		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	0		
From 65-84 years	0		
85 years and over	0		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female			
Units: Participants			
Female	1066		
Male	72		
Unknown	26		
Ethnicity (NIH/OMB)			
Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP) issues			
Units: Subjects			
Hispanic or Latino	357		
Not Hispanic or Latino	687		
Unknown or Not Reported	120		
Race (NIH/OMB)			
Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP) issues			
Units: Subjects			
American Indian or Alaska Native	187		
Asian	195		

Native Hawaiian or Other Pacific Islander	1		
Black or African American	120		
White	627		
More than one race	8		
Unknown or Not Reported	26		
Region of Enrollment			
Units: Subjects			
Colombia	44		
Argentina	66		
Puerto Rico	21		
Singapore	2		
United States	377		
Philippines	62		
Japan	45		
Egypt	59		
Ukraine	74		
Thailand	34		
Belarus	12		
Canada	4		
Austria	7		
Macedonia, The Former Yugoslav Republic of	12		
Poland	54		
Guatemala	43		
Korea, Republic of	43		
Italy	10		
Bulgaria	31		
Chile	13		
Peru	99		
Germany	24		
Croatia	2		
Unknown	26		
At Least One BILAG A or Two BILAG B Disease Activity Scores			
The British Isles Lupus Assessment Group (BILAG) instrument assesses global disease activity across 9 organ system domains and assessed for each of the 9 organ domains using BILAG2004 index flare rules; A is a severe flare and B is a moderate flare. The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group because not all participants will have at least one BILAG A or Two BILAG B Disease Activity scores.			
Units: Subjects			
Yes	1047		
No	90		
Unknown	27		
Anti-dsDNA Antibody Level			
Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP) issues			
Units: International Units/Milliliter (IU/mL)			
arithmetic mean			
standard deviation	-		
Safety of Estrogens in Lupus Erythematosus National Assessment			

(SELENA-SLEDAI) Score			
SELENA SLEDAI is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105; scores > 20 are rare. PGA is a visual analog scale scored from 0 to 3 (0=none, 1=mild, 2=moderate, 3=severe). Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP) issues			
Units: units on a scale arithmetic mean standard deviation	-		
Physician's Global Assessment (PGA) Score			
PGA is a single-item clinician rated assessment of the participant's current level of disease activity measured on a continuous 100-millimeter (mm) visual analytic scale with benchmarks of 0, 1, 2, and 3 from left to right corresponding to no, mild, moderate, and severe SLE disease activity. Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP).			
Units: units on a scale arithmetic mean standard deviation	-		
Time of Onset of Lupus			
Intent to Treat population (ITT) is all randomized participants who received at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP) issues			
Units: years arithmetic mean standard deviation	-		
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Physical Health			
34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) with SLE within 8 domains: physical health (8 items), emotional health (6 items), body image (5 items), pain (3 items), planning (3 items), fatigue (4 items), intimate relationships (2 items), and burden to others (3 items). Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites which were excluded due to suspected GCP practices.			
Units: units on a scale (transformed) arithmetic mean standard deviation	-		
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Emotional Health			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationships (2 items), and burden to others (3 items). Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed) arithmetic mean standard deviation	-		
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Body Image			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health (8 items), emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed)			

arithmetic mean			
standard deviation	-		
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Pain			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed)			
arithmetic mean			
standard deviation	-		
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Planning			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed)			
arithmetic mean			
standard deviation	-		
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Fatigue			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed)			
arithmetic mean			
standard deviation	-		
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Intimate Relationships			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed)			
arithmetic mean			
standard deviation	-		
Lupus Quality of Life (lupus QOL) Composite and Domain Scores Burden to Others			
The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within 8 domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationships, and burden to others. Responses are based on a 5-point Likert scale where 0 = "all the time", 1 = "most of the time", 2 = "a good bit of the time", 3 = "occasionally", and 4 = "never". ITT excludes 2 sites due to suspected GCP issues.			
Units: units on a scale (transformed)			
arithmetic mean			
standard deviation	-		
Brief Fatigue Inventory (BFI) Score (Worst Level of Fatigue in the Last 24 Hours)			
BFI is a participants-reported scale that measures the severity of fatigue based on the worst fatigue experienced during the past 24-hours. The severity scores ranged from 0 (no fatigue) to 10 (fatigue as severe as you can imagine). Intent to Treat population (ITT) is all randomized participants who received			

at least 1 dose of study drug, excluding two sites' participants due to good clinical practice (GCP) issues.			
Units: units on a scale arithmetic mean standard deviation	-		

End points

End points reporting groups

Reporting group title	LY2127399 every 2 weeks
Reporting group description: LY2127399: 120 mg administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug.	
Reporting group title	LY2127399 every 4 wks
Reporting group description: During the Treatment Period, for blinding purposes, patients will alternate injections of LY2127399 and injections of placebo every 2 weeks. LY2127399: 120 mg administered via subcutaneous injection for 52 weeks. 240 mg loading dose will be administered as the first dose of study drug. Placebo every 4 weeks: Administered via subcutaneous injection for 52 weeks.	
Reporting group title	Placebo
Reporting group description: Placebo every 2 weeks: Administered via subcutaneous injection for 52 weeks. A matching loading dose will also be administered at the first dose	

Primary: Percentage of Participants Achieving an SLE Responder Index Response at Week 52

End point title	Percentage of Participants Achieving an SLE Responder Index Response at Week 52
End point description: Percentage of participants with a ≥ 5 point reduction from baseline in SELENA SLEDAI score, and no worsening (increase of < 0.30 points from baseline) in PGA, and no new BILAG A organ domain score or 2 new BILAG B organ domain scores compared with baseline. SELENA SLEDAI is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105; scores > 20 are rare. PGA is a visual analog scale scored from 0 to 3 (0=none, 1=mild, 2=moderate, 3=severe). BILAG uses a single score for each of the 9 organ domains; range is from severe (A) to no disease (E). Analysis Population Description (APD): Participants who were unable to comply with allowed concomitant medications requirements were considered non-responders, as were participants who dropped out or were missing Week 52 data.	
End point type	Primary
End point timeframe: 52 weeks	

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	381 ^[1]	378 ^[2]	379 ^[3]	
Units: percentage of participants				
number (not applicable)	121	133	111	

Notes:

[1] - Participants who received at least 1 dose of study drug, excluding two sites for GCP issues.

[2] - Participants who received at least 1 dose of study drug, excluding two sites for GCP issues.

[3] - Participants who received at least 1 dose of study drug, excluding two sites for GCP issues.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	LY2127399 every 2 weeks v LY2127399 every 4 wks v Placebo
Number of subjects included in analysis	1138
Analysis specification	Pre-specified
Analysis type	other ^[4]
P-value	= 0.05
Method	Chi-squared

Notes:

[4] - Efficacy and PRO variables that were both continuous and measured at multiple visits were analyzed using MMRM. This model added visit and visit-by-treatment interaction as fixed effects. The least square (LS) means and corresponding CIs and p-values were estimated using an analysis of covariance (ANCOVA) model.

Secondary: Percentage Participants Able to Decrease Dose of Prednisone or Equivalent with No Increase in Disease Activity at Week 52

End point title	Percentage Participants Able to Decrease Dose of Prednisone or Equivalent with No Increase in Disease Activity at Week 52
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End point description:

A participant achieves corticosteroid sparing effects (quiescent disease) if they have met the following criteria during Weeks 24 through 52; able to decrease their dose of prednisone or equivalent to 7.5 mg/day or less, have quiescent disease (BILAG C score or better in all nine systems), and no BILAG A or B flares in the previous three months, without an increase in either antimalarials or immunosuppressants on or prior to the visit. Only participants receiving a prednisone or equivalent dose of more than 7.5 mg/day at baseline are included. APD: All randomized participants who received at least 1 dose of study drug, a baseline use of prednisone or equivalent >7.5 mg/day, excluding two sites' participants due to good clinical practice (GCP) issues.

End point type	Secondary
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End point timeframe:

52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	197 ^[5]	200 ^[6]	196 ^[7]	
Units: percentage of participants				
number (not applicable)	15.5	17.0	16.4	

Notes:

[5] - See description

[6] - See description

[7] - See description

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to 52 weeks in anti-double stranded deoxyribonucleic acid (anti-dsDNA) level

End point title	Change from baseline to 52 weeks in anti-double stranded deoxyribonucleic acid (anti-dsDNA) level
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End point description:

Anti-double stranded deoxyribonucleic acid (anti-dsDNA) is a lab analyte used to assist in the diagnosis of SLE. APD: All randomized participants who received at least 1 dose of study drug, a baseline use of prednisone or equivalent >7.5 mg/day, excluding two sites' participants due to good clinical practice (GCP) issues.

End point type	Secondary
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End point timeframe:

Baseline, 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	381 ^[8]	378 ^[9]	377 ^[10]	
Units: international units				
arithmetic mean (standard deviation)	107.2 (± 113.50)	110.4 (± 111.58)	107.1 (± 112.40)	

Notes:

[8] - See description.

[9] - See description.

[10] - See description.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to 52 week endpoint in Systemic Lupus Erythematosus Disease Activity Index (SLEDAI2K) score

End point title	Change from baseline to 52 week endpoint in Systemic Lupus Erythematosus Disease Activity Index (SLEDAI2K) score
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End point description:

SLE Disease Activity Index 2000 (SLEDAI-2K) score is a weighted, cumulative index of lupus disease activity. SLEDAI-2K is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105.

End point type	Secondary
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End point timeframe:

Baseline, 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	377 ^[11]	374 ^[12]	376 ^[13]	
Units: units on a scale				
arithmetic mean (standard deviation)	-4.7 (± 4.35)	-4.9 (± 4.32)	-4.6 (± 4.54)	

Notes:

[11] - All participants who received at least 1 dose of study drug and had a SLEDAI2K score.

[12] - All participants who received at least 1 dose of study drug and had a SLEDAI2K score.

[13] - All participants who received at least 1 dose of study drug and had a SLEDAI2K score.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to first severe SLE flare (SFI)

End point title	Time to first severe SLE flare (SFI)
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End point description:

The SFI uses the SELENA-SLEDAI disease activity index score, disease activity scenarios, treatment changes, and PGA to define mild/moderate and severe flares. The index takes into account the absolute change in total scores, new or worsening symptoms, and increases in corticosteroid use or hospitalization due to the disease activity.

Time to first severe SLE flare (SFI) (in days) is calculated as: (Start date of first severe SLE flare (SFI) - Date of randomization + 1).

End point type	Secondary
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End point timeframe:

Baseline through 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[14]	0 ^[15]	0 ^[16]	
Units: Years				
number (not applicable)				

Notes:

[14] - Zero participants analyzed. Due to product program termination, analyses were not completed.

[15] - Zero participants analyzed. Due to product program termination, analyses were not completed.

[16] - Zero participants analyzed. Due to product program termination, analyses were not completed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with No Worsening in Physician Global Assessment (PGA) Score at 52 Weeks

End point title	Percentage of Participants with No Worsening in Physician Global Assessment (PGA) Score at 52 Weeks
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End point description:

Physician's Global Assessment (PGA) is a single-item clinician rated assessment of the patient's current level of disease activity measured on a continuous 100 millimeter (mm) visual analytic scale with benchmarks of 0, 1, 2, and 3 from left to right corresponding to no, mild, moderate, and severe SLE disease activity. Scores are presented from 0 to 100.

End point type	Secondary
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End point timeframe:

52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	381 ^[17]	378 ^[18]	379 ^[19]	
Units: percentage of participants				
number (not applicable)	64.3	61.4	58.0	

Notes:

[17] - Participants who had 1 dose of study drug and a PGA score, excluding 2 sites for GCP issues.

[18] - Participants who had 1 dose of study drug and a PGA score, excluding 2 sites for GCP issues.

[19] - Participants who had 1 dose of study drug and a PGA score, excluding 2 sites for GCP issues.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to 52 week endpoint in Brief Fatigue Inventory (BFI) scores

End point title	Change from baseline to 52 week endpoint in Brief Fatigue Inventory (BFI) scores
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End point description:

A participants-reported scale that measures the severity of fatigue based on the worst fatigue experienced during the past 24-hours. The severity scores ranged from 0 (no fatigue) to 10 (fatigue as severe as you can imagine).

End point type	Secondary
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End point timeframe:

Baseline, 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	362 ^[20]	363 ^[21]	361 ^[22]	
Units: units on a scale				
arithmetic mean (standard deviation)	-0.9 (± 3.09)	-0.9 (± 3.14)	-0.6 (± 2.86)	

Notes:

[20] - Randomized participants who received 1 dose of study drug and had a BFI score at 52 weeks.

[21] - Randomized participants who received 1 dose of study drug and had a BFI score at 52 weeks.

[22] - Randomized participants who received 1 dose of study drug and had a BFI score at 52 weeks.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 52 Week Endpoint Lupus Quality of Life (LupusQoL) Composite and Domain scores

End point title	Change from Baseline to 52 Week Endpoint Lupus Quality of Life (LupusQoL) Composite and Domain scores
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End point description:

The LupusQoL is a disease-specific, 34-item, self-report questionnaire designed to measure the health-related quality of life (HRQoL) of participants with SLE within the following 8 domains: physical health, emotional health, body language, pain, planning, fatigue, intimate relationships, burden to others.

End point type	Secondary
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End point timeframe:

Baseline, 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	381 ^[23]	378 ^[24]	361 ^[25]	
Units: units on a scale				
arithmetic mean (standard deviation)				
Physical Health (n=121,133,111)	73.7 (± 26.05)	72.8 (± 24.53)	72.8 (± 23.70)	
Emotional Health (n=121,133,111)	75.2 (± 25.50)	72.4 (± 24.08)	73.1 (± 25.54)	
Body Language (n=117,131,108)	75.1 (± 26.21)	75.0 (± 24.82)	71.9 (± 28.90)	
Pain (n=121,133,111)	74.0 (± 27.42)	74.1 (± 24.94)	73.2 (± 27.30)	
Planning (n=121,133,111)	77.3 (± 26.53)	75.0 (± 29.07)	74.5 (± 28.93)	
Fatigue(n=121,133,111)	70.4 (± 25.51)	68.8 (± 26.34)	64.5 (± 24.94)	
Intimate Relationships (n=100,124,101)	77.4 (± 29.01)	68.8 (± 34.06)	68.7 (± 30.08)	
Burden to Others(n=121,133,111)	68.7 (± 30.43)	63.5 (± 30.34)	63.7 (± 30.21)	

Notes:

[23] - Randomized participants who received 1 dose of study drug and had a score at Week 52.

[24] - Randomized participants who received 1 dose of study drug and had a score at Week 52.

[25] - Randomized participants who received 1 dose of study drug and had a score at Week 52.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to first new British Isles Lupus Assessment Group (BILAG A) or 2 new BILAG B SLE flares

End point title	Time to first new British Isles Lupus Assessment Group (BILAG A) or 2 new BILAG B SLE flares
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End point description:

The British Isles Lupus Assessment Group (BILAG) instrument assesses global disease activity across 9 organ system domains. BILAG flare is assessed for each of the 9 organ domains using BILAG2004 index flare rules; A is a severe flare and B is a moderate flare.

Time to first BILAG A or two BILAG B flares (in days) is calculated as: (Start date of first BILAG A or two BILAG B flares - Date of randomization + 1). The two BILAG B flares must occur in different domains at the same visit.

End point type	Secondary
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End point timeframe:

Baseline through 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[26]	0 ^[27]	0 ^[28]	
Units: Years				
number (not applicable)				

Notes:

[26] - Zero participants analyzed. Due to product program termination, analyses were not completed.

[27] - Zero participants analyzed. Due to product program termination, analyses were not completed.

[28] - Zero participants analyzed. Due to product program termination, analyses were not completed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to 52 Week Endpoint in PGA

End point title	Change from Baseline to 52 Week Endpoint in PGA
End point description:	
Physician's Global Assessment (PGA) is a single-item clinician rated assessment of the patient's current level of disease activity measured on a continuous 100-mm visual analytic scale with benchmarks of 0, 1, 2, and 3 from left to right corresponding to no, mild, moderate, and severe SLE disease activity.	
End point type	Secondary
End point timeframe:	
Baseline, 52 weeks	

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	375 ^[29]	374 ^[30]	375 ^[31]	
Units: millimeters				
arithmetic mean (standard deviation)	-20.8 (± 21.97)	-20.8 (± 22.33)	-20.2 (± 22.42)	

Notes:

[29] - Randomized participants who received 1 dose of study drug and had a PGA score at Week 52.

[30] - Randomized participants who received 1 dose of study drug and had a PGA score at Week 52.

[31] - Randomized participants who received 1 dose of study drug and had a PGA score at Week 52.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with an Increase in Corticosteroids Dose at 52 Weeks

End point title	Percentage of Participants with an Increase in Corticosteroids Dose at 52 Weeks
End point description:	
An increase in corticosteroids at a visit was defined as a change from baseline greater than 2.5 mg/day in dose or prednisone or equivalent using average daily dose of corticosteroids taken since the previous scheduled visit.	
End point type	Secondary
End point timeframe:	
52 weeks	

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	381 ^[32]	378 ^[33]	196 ^[34]	
Units: percentage of participants				
number (not applicable)	6.7	9.1	8.8	

Notes:

[32] - Randomized participants with 1 dose of study drug,an increase in corticosteroid dose.

[33] - Randomized participants with 1 dose of study drug,an increase in corticosteroid dose.

[34] - Randomized participants with 1 dose of study drug,an increase in corticosteroid dose.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to 52 weeks endpoint in SELENA-SLEDAI disease activity score

End point title	Change from baseline to 52 weeks endpoint in SELENA-SLEDAI disease activity score
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End point description:

Safety of Estrogens in Lupus Erythematosus National Assessment - SLE Disease Activity Index (SELENA-SLEDAI) score is a weighted, cumulative index of lupus disease activity. SELENA-SLEDAI is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105.

End point type	Secondary
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End point timeframe:

Baseline, 52 weeks

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	381 ^[35]	378 ^[36]	376 ^[37]	
Units: units on a scale				
arithmetic mean (standard deviation)	-4.6 (± 4.19)	-4.7 (± 4.11)	-4.8 (± 4.47)	

Notes:

[35] - All participants who received at least 1 dose of study drug and had an activity score.

[36] - All participants who received at least 1 dose of study drug and had an activity score.

[37] - All participants who received at least 1 dose of study drug and had an activity score.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a Response as Measured by Modified SRI with No BILAG A or No More than 1 BILAG B Organ Domain Flares at 52 Weeks

End point title	Percentage of Participants Achieving a Response as Measured by Modified SRI with No BILAG A or No More than 1 BILAG B Organ Domain Flares at 52 Weeks
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End point description:

Percentage of participants with a ≥ 5 point reduction from baseline in SELENA SLEDAI score, and no worsening (increase of < 0.30 points from baseline) in PGA, and no new BILAG A or no more than 1 new BILAG B organ domain flare compared with baseline. (Primary outcome modified to use BILAG flare

instead of BILAG disease score)

SELENA SLEDAI is calculated from 24 individual descriptors across 9 organ systems; 0 indicates inactive disease and the maximum theoretical score is 105. PGA is a visual analog scale scored from 0 to 3 (0=none, 1=mild, 2=moderate, 3=severe). BILAG flare is assessed for each of the 9 organ domains; A is a severe flare and B is a moderate flare. Patients who were unable to comply with allowed concomitant medications requirements were considered non-responders, as were participants who dropped out or were missing Week 52 data.

End point type	Secondary
End point timeframe:	
52 weeks	

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	381 ^[38]	378 ^[39]	379 ^[40]	
Units: percentage of participants				
number (not applicable)				
Responder	31.8	35.2	29.6	
Non-Responder	68.2	64.8	70.4	

Notes:

[38] - Randomized participants who had 1 dose of study drug, excluding 2 sites due to GCP issues.

[39] - Randomized participants who had 1 dose of study drug, excluding 2 sites due to GCP issues.

[40] - Randomized participants who had 1 dose of study drug, excluding 2 sites due to GCP issues.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With No New BILAG A and No More Than One New BILAG B Disease Activity Scores Compared to Baseline

End point title	Number of Participants With No New BILAG A and No More Than One New BILAG B Disease Activity Scores Compared to Baseline
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End point description:

The BILAG2004 index is a validated global disease activity index designed on the basis of the physician's ITT, focusing on changes in disease manifestations (new, improved, worsening, etc) occurring in the last 4 weeks compared with the previous 4 weeks.

The instrument assesses 97 clinical signs, symptoms, and laboratory parameters across 9 organ system domains: constitutional, mucocutaneous, neuropsychiatric, musculoskeletal, cardiorespiratory, gastrointestinal, ophthalmic, renal and hematology.

End point type	Secondary
End point timeframe:	
Baseline through 52 weeks	

End point values	LY2127399 every 2 weeks	LY2127399 every 4 wks	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	381 ^[41]	378 ^[42]	379 ^[43]	
Units: participants				
number (not applicable)	247	234	219	

Notes:

[41] - Randomized participants who had 1 dose of study drug, excluding 2 sites due to GCP issues.

[42] - Randomized participants who had 1 dose of study drug, excluding 2 sites due to GCP issues.

[43] - Randomized participants who had 1 dose of study drug, excluding 2 sites due to GCP issues.

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-BCDS

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.0
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Reporting groups

Reporting group title	LY 120 mg Q2W Treatment Period
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Reporting group description: -

Reporting group title	LY 120 mg Q4W Treatment Period
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Reporting group description: -

Reporting group title	Placebo Treatment Period
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Reporting group description: -

Reporting group title	LY 120 mg Q2W Follow-up Period
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Reporting group description: -

Reporting group title	LY 120 mg Q4W Follow-up Period
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Reporting group description: -

Reporting group title	Placebo Follow-up Period
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Reporting group description: -

Serious adverse events	LY 120 mg Q2W Treatment Period	LY 120 mg Q4W Treatment Period	Placebo Treatment Period
Total subjects affected by serious adverse events			
subjects affected / exposed	42 / 386 (10.88%)	56 / 389 (14.40%)	50 / 387 (12.92%)
number of deaths (all causes)	3	2	2
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
brenner tumour			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed ^[1]	1 / 359 (0.28%)	0 / 362 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemangioma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
intestinal adenocarcinoma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[2]	1 / 359 (0.28%)	0 / 362 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
femoral artery occlusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
haematoma			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 386 (0.52%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
female sterilisation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[3]	0 / 359 (0.00%)	0 / 362 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[4]	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pre-eclampsia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[5]	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
death			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
generalised oedema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	2 / 387 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
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			
type iii immune complex mediated reaction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
adenomyosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[6]	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ovarian cyst			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed ^[7]	1 / 359 (0.28%)	1 / 362 (0.28%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ovarian cyst ruptured			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[8]	1 / 359 (0.28%)	0 / 362 (0.00%)	0 / 368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pelvic pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
atelectasis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	1 / 389 (0.26%)	2 / 387 (0.52%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 386 (0.26%)	1 / 389 (0.26%)	2 / 387 (0.52%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleuritic pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
respiratory failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
affect lability			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
affective disorder			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anxiety			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
depression			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
generalised anxiety disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
major depression			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
mental disorder due to a general medical condition			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
psychotic disorder			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
haemoglobin decreased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
weight increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
compression fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
fall			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 386 (0.00%)	3 / 389 (0.77%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
humerus fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
incisional hernia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
medication error			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
overdose			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

spinal fracture alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 386 (0.00%) 0 / 0 0 / 0	0 / 389 (0.00%) 0 / 0 0 / 0	1 / 387 (0.26%) 0 / 1 0 / 0
tendon rupture alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 386 (0.26%) 0 / 1 0 / 0	0 / 389 (0.00%) 0 / 0 0 / 0	0 / 387 (0.00%) 0 / 0 0 / 0
thoracic vertebral fracture alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 386 (0.00%) 0 / 0 0 / 0	1 / 389 (0.26%) 0 / 1 0 / 0	0 / 387 (0.00%) 0 / 0 0 / 0
toxicity to various agents alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 386 (0.26%) 0 / 1 0 / 0	0 / 389 (0.00%) 0 / 0 0 / 0	0 / 387 (0.00%) 0 / 0 0 / 0
wrist fracture alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 386 (0.00%) 0 / 0 0 / 0	1 / 389 (0.26%) 0 / 1 0 / 0	0 / 387 (0.00%) 0 / 0 0 / 0
Congenital, familial and genetic disorders sickle cell anaemia with crisis alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 386 (0.00%) 0 / 0 0 / 0	0 / 389 (0.00%) 0 / 0 0 / 0	1 / 387 (0.26%) 1 / 1 0 / 0
Cardiac disorders acute myocardial infarction			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
atrioventricular block complete			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
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 arrest			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
cardiac failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
cardiac failure congestive			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 386 (0.52%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	2 / 387 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lupus endocarditis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
mitral valve prolapse			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocarditis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
pericarditis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
supraventricular tachycardia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular fibrillation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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			
central nervous system inflammation			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
cerebral venous thrombosis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
cerebrovascular accident alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
convulsion alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
ischaemic stroke alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
migraine alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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

neuropsychiatric lupus alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
radiculopathy alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vasculitis cerebral alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
vertebrobasilar insufficiency alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
antiphospholipid syndrome alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
autoimmune haemolytic anaemia alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
febrile neutropenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
haemorrhagic anaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
histiocytosis haematophagic			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
leukopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutropenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombocytopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	2 / 389 (0.51%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

thrombocytosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal hernia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
constipation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
enterocolitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
gastric ulcer			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
gastritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 386 (0.52%)	1 / 389 (0.26%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis atrophic			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal inflammation alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
gastrooesophageal reflux disease alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obstruction gastric alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
pancreatitis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	1 / 389 (0.26%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

rectal ulcer alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
varices oesophageal alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
vasculitis gastrointestinal alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis acute alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
cholelithiasis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
hepatic steatosis alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
cutaneous lupus erythematosus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
erythema multiforme			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypersensitivity vasculitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
systemic lupus erythematosus rash			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
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 ureteric			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
glomerulonephritis proliferative			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
lupus cystitis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
lupus nephritis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 386 (0.52%)	1 / 389 (0.26%)	4 / 387 (1.03%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mesangioproliferative glomerulonephritis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
nephrotic syndrome alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure chronic			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
cervical spinal stenosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 386 (0.00%)	2 / 389 (0.51%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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 chest pain alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	2 / 389 (0.51%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	1 / 389 (0.26%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteonecrosis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain in extremity alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
polyarthrititis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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

sle arthritis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
systemic lupus erythematosus alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 386 (0.52%)	4 / 389 (1.03%)	5 / 387 (1.29%)
occurrences causally related to treatment / all	0 / 2	0 / 4	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
tendon disorder alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess limb alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 386 (0.52%)	1 / 389 (0.26%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis bacterial alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
bronchitis alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	2 / 387 (0.52%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	2 / 389 (0.51%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
disseminated tuberculosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
diverticulitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis norovirus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

gastroenteritis viral				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
haematoma infection				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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	
herpes zoster				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
infected skin ulcer				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
klebsiella bacteraemia				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
lung infection				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
mycobacterial infection				
alternative dictionary used: MedDRA 17.0				

subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oral candidiasis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
osteomyelitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	1 / 389 (0.26%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreas infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
parotitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
pharyngotonsillitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	5 / 386 (1.30%)	8 / 389 (2.06%)	4 / 387 (1.03%)
occurrences causally related to treatment / all	2 / 5	3 / 9	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

pneumonia viral			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
pyelonephritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	1 / 389 (0.26%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
salpingo-oophoritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[9]	0 / 359 (0.00%)	0 / 362 (0.00%)	1 / 368 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinusitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
sinusitis bacterial			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (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
staphylococcal skin infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
superinfection bacterial			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

tracheobronchitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 386 (0.52%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	3 / 386 (0.78%)	1 / 389 (0.26%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	7 / 386 (1.81%)	2 / 389 (0.51%)	1 / 387 (0.26%)
occurrences causally related to treatment / all	1 / 7	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	1 / 389 (0.26%)	0 / 387 (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
Metabolism and nutrition disorders			
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	1 / 389 (0.26%)	0 / 387 (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
fluid overload			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 386 (0.00%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyponatraemia			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 386 (0.26%)	0 / 389 (0.00%)	0 / 387 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	LY 120 mg Q2W Follow-up Period	LY 120 mg Q4W Follow-up Period	Placebo Follow-up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 103 (9.71%)	9 / 105 (8.57%)	17 / 128 (13.28%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
brenner tumour			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[1]	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemangioma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intestinal adenocarcinoma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 17.0			

subjects affected / exposed ^[2]	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral artery occlusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematoma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
female sterilisation			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed ^[3]	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[4]	0 / 97 (0.00%)	0 / 99 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pre-eclampsia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[5]	0 / 97 (0.00%)	0 / 99 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
death			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
generalised oedema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
Immune system disorders			
type iii immune complex mediated reaction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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			
adenomyosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[6]	0 / 97 (0.00%)	1 / 99 (1.01%)	0 / 119 (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
ovarian cyst			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[7]	0 / 97 (0.00%)	1 / 99 (1.01%)	0 / 119 (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
ovarian cyst ruptured			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[8]	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pelvic pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used:			

MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atelectasis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleuritic pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
pneumonitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 failure alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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			
affect lability alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
affective disorder alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
anxiety alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
generalised anxiety disorder alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
major depression			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mental disorder due to a general medical condition			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
psychotic disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
haemoglobin decreased			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
weight increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
incisional hernia			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
medication error			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
overdose			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 17.0			
subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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 fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thoracic vertebral fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

toxicity to various agents alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
sickle cell anaemia with crisis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 failure			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 failure congestive			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
coronary artery disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lupus endocarditis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mitral valve prolapse			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocarditis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 17.0			

subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
supraventricular tachycardia alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular fibrillation alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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			
central nervous system inflammation alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral venous thrombosis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 17.0			
subjects affected / exposed	1 / 103 (0.97%)	1 / 105 (0.95%)	0 / 128 (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
convulsion alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
migraine			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neuropsychiatric lupus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	1 / 105 (0.95%)	0 / 128 (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
radiculopathy			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	1 / 105 (0.95%)	0 / 128 (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
syncope			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

vasculitis cerebral alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertebrobasilar insufficiency alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
antiphospholipid syndrome alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
autoimmune haemolytic anaemia alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
febrile neutropenia alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhagic anaemia alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
histiocytosis haematophagic alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
neutropenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
thrombocytopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombocytosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal hernia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
constipation			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
enterocolitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis atrophic			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 inflammation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obstruction gastric alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 ulcer alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
varices oesophageal alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vasculitis gastrointestinal alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 103 (0.00%)	1 / 105 (0.95%)	0 / 128 (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
vomiting			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic steatosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
cutaneous lupus erythematosus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erythema multiforme			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
hypersensitivity vasculitis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
systemic lupus erythematosus rash alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
calculus ureteric alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerulonephritis proliferative alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lupus cystitis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lupus nephritis alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	2 / 103 (1.94%)	0 / 105 (0.00%)	3 / 128 (2.34%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mesangioproliferative glomerulonephritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrotic syndrome			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	1 / 105 (0.95%)	0 / 128 (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 failure chronic			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervical spinal stenosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 chest pain			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteonecrosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain in extremity			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	1 / 105 (0.95%)	0 / 128 (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
polyarthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sle arthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
systemic lupus erythematosus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 103 (3.88%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

tendon disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess limb			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
appendicitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis bacterial			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	1 / 105 (0.95%)	0 / 128 (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
bronchitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 17.0			
subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
device related infection			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
disseminated tuberculosis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis norovirus alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematoma infection alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

herpes zoster			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infected skin ulcer			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
klebsiella bacteraemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	1 / 105 (0.95%)	0 / 128 (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
mycobacterial infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
oral candidiasis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteomyelitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreas infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
parotitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pharyngotonsillitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	1 / 105 (0.95%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia viral			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
post procedural infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pyelonephritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
salpingo-oophoritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[9]	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	1 / 105 (0.95%)	0 / 128 (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
sinusitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinusitis bacterial			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal bacteraemia alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal infection alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal skin infection alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
superinfection bacterial alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tracheobronchitis alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
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 respiratory tract infection alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fluid overload			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (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
hyponatraemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Notes:

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

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

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

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed to this adverse event. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

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

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

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

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

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

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

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

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

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

Justification: 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 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	LY 120 mg Q2W Treatment Period	LY 120 mg Q4W Treatment Period	Placebo Treatment Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	253 / 386 (65.54%)	244 / 389 (62.72%)	248 / 387 (64.08%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	14 / 386 (3.63%)	13 / 389 (3.34%)	20 / 387 (5.17%)
occurrences (all)	14	13	21
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[10]	3 / 359 (0.84%)	2 / 362 (0.55%)	4 / 368 (1.09%)
occurrences (all)	3	2	4
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed occurrences (all)	10 / 386 (2.59%) 12	15 / 389 (3.86%) 16	10 / 387 (2.58%) 11
injection site reaction alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	11 / 386 (2.85%) 17	7 / 389 (1.80%) 10	6 / 387 (1.55%) 8
oedema peripheral alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	11 / 386 (2.85%) 11	8 / 389 (2.06%) 9	10 / 387 (2.58%) 11
pyrexia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	8 / 386 (2.07%) 9	10 / 389 (2.57%) 14	8 / 387 (2.07%) 16
Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	10 / 386 (2.59%) 11	12 / 389 (3.08%) 13	18 / 387 (4.65%) 18
Psychiatric disorders anxiety alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) depression alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) insomnia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	6 / 386 (1.55%) 7 7 / 386 (1.81%) 7 22 / 386 (5.70%) 22	8 / 389 (2.06%) 8 12 / 389 (3.08%) 13 17 / 389 (4.37%) 17	6 / 387 (1.55%) 7 12 / 387 (3.10%) 12 16 / 387 (4.13%) 17
Injury, poisoning and procedural complications			

testicular injury alternative dictionary used: MedDRA 17.0 subjects affected / exposed ^[11] occurrences (all)	0 / 27 (0.00%) 0	0 / 27 (0.00%) 0	1 / 19 (5.26%) 1
Nervous system disorders dizziness alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) headache alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	6 / 386 (1.55%) 6 34 / 386 (8.81%) 48	19 / 389 (4.88%) 31 35 / 389 (9.00%) 56	15 / 387 (3.88%) 15 45 / 387 (11.63%) 54
Eye disorders dry eye alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	8 / 386 (2.07%) 8	3 / 389 (0.77%) 3	1 / 387 (0.26%) 1
Gastrointestinal disorders abdominal pain alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) abdominal pain upper alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) constipation alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) diarrhoea alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) dyspepsia	8 / 386 (2.07%) 8 10 / 386 (2.59%) 11 11 / 386 (2.85%) 11 22 / 386 (5.70%) 26	12 / 389 (3.08%) 14 11 / 389 (2.83%) 12 7 / 389 (1.80%) 7 29 / 389 (7.46%) 33	12 / 387 (3.10%) 12 11 / 387 (2.84%) 11 11 / 387 (2.84%) 11 23 / 387 (5.94%) 30

alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	8 / 386 (2.07%) 9	8 / 389 (2.06%) 8	10 / 387 (2.58%) 17
gastritis alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	12 / 386 (3.11%) 13	6 / 389 (1.54%) 6	7 / 387 (1.81%) 7
gastrooesophageal reflux disease alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	11 / 386 (2.85%) 11	7 / 389 (1.80%) 7	7 / 387 (1.81%) 9
nausea alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	17 / 386 (4.40%) 19	31 / 389 (7.97%) 42	21 / 387 (5.43%) 24
vomiting alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	16 / 386 (4.15%) 19	14 / 389 (3.60%) 17	11 / 387 (2.84%) 12
Skin and subcutaneous tissue disorders rash alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	5 / 386 (1.30%) 5	6 / 389 (1.54%) 6	10 / 387 (2.58%) 11
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	14 / 386 (3.63%) 15	15 / 389 (3.86%) 17	11 / 387 (2.84%) 14
back pain alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	15 / 386 (3.89%) 15	28 / 389 (7.20%) 30	19 / 387 (4.91%) 24
muscle spasms alternative dictionary used:			

MedDRA 17.0			
subjects affected / exposed	4 / 386 (1.04%)	8 / 389 (2.06%)	7 / 387 (1.81%)
occurrences (all)	5	8	7
musculoskeletal chest pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 386 (0.52%)	8 / 389 (2.06%)	8 / 387 (2.07%)
occurrences (all)	2	8	8
musculoskeletal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 386 (0.26%)	6 / 389 (1.54%)	10 / 387 (2.58%)
occurrences (all)	1	6	12
myalgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	9 / 386 (2.33%)	6 / 389 (1.54%)	9 / 387 (2.33%)
occurrences (all)	11	6	9
pain in extremity			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	7 / 386 (1.81%)	5 / 389 (1.29%)	8 / 387 (2.07%)
occurrences (all)	8	7	9
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	15 / 386 (3.89%)	19 / 389 (4.88%)	17 / 387 (4.39%)
occurrences (all)	18	19	19
conjunctivitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	9 / 386 (2.33%)	8 / 389 (2.06%)	6 / 387 (1.55%)
occurrences (all)	11	10	6
cystitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 386 (1.04%)	8 / 389 (2.06%)	9 / 387 (2.33%)
occurrences (all)	5	8	10
gastroenteritis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	10 / 386 (2.59%)	9 / 389 (2.31%)	11 / 387 (2.84%)
occurrences (all)	11	10	12
herpes zoster			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	13 / 386 (3.37%)	4 / 389 (1.03%)	9 / 387 (2.33%)
occurrences (all)	13	5	9
influenza			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	9 / 386 (2.33%)	5 / 389 (1.29%)	6 / 387 (1.55%)
occurrences (all)	10	5	6
nasopharyngitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	29 / 386 (7.51%)	33 / 389 (8.48%)	37 / 387 (9.56%)
occurrences (all)	46	35	48
oral candidiasis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	6 / 386 (1.55%)	3 / 389 (0.77%)	8 / 387 (2.07%)
occurrences (all)	7	3	9
pharyngitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	13 / 386 (3.37%)	18 / 389 (4.63%)	14 / 387 (3.62%)
occurrences (all)	17	19	18
sinusitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	16 / 386 (4.15%)	15 / 389 (3.86%)	11 / 387 (2.84%)
occurrences (all)	22	16	11
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	55 / 386 (14.25%)	41 / 389 (10.54%)	51 / 387 (13.18%)
occurrences (all)	86	55	72
urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	68 / 386 (17.62%)	52 / 389 (13.37%)	51 / 387 (13.18%)
occurrences (all)	100	76	77

vulvovaginal mycotic infection alternative dictionary used: MedDRA 17.0 subjects affected / exposed ^[12] occurrences (all)	7 / 359 (1.95%) 7	9 / 362 (2.49%) 12	8 / 368 (2.17%) 11
Metabolism and nutrition disorders hypertriglyceridaemia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	8 / 386 (2.07%) 9	4 / 389 (1.03%) 5	2 / 387 (0.52%) 2
hypokalaemia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	9 / 386 (2.33%) 11	1 / 389 (0.26%) 1	3 / 387 (0.78%) 4

Non-serious adverse events	LY 120 mg Q2W Follow-up Period	LY 120 mg Q4W Follow-up Period	Placebo Follow-up Period
Total subjects affected by non-serious adverse events subjects affected / exposed	21 / 103 (20.39%)	23 / 105 (21.90%)	23 / 128 (17.97%)
Vascular disorders hypertension alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	4 / 103 (3.88%) 4	0 / 105 (0.00%) 0	0 / 128 (0.00%) 0
Pregnancy, puerperium and perinatal conditions pregnancy alternative dictionary used: MedDRA 17.0 subjects affected / exposed ^[10] occurrences (all)	0 / 97 (0.00%) 0	2 / 99 (2.02%) 2	1 / 119 (0.84%) 1
General disorders and administration site conditions fatigue alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 105 (0.00%) 0	1 / 128 (0.78%) 1
injection site reaction alternative dictionary used: MedDRA 17.0			

subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 105 (0.00%) 0	0 / 128 (0.00%) 0
oedema peripheral alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 105 (0.00%) 0	0 / 128 (0.00%) 0
pyrexia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 105 (0.00%) 0	1 / 128 (0.78%) 1
Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	2 / 105 (1.90%) 3	1 / 128 (0.78%) 1
Psychiatric disorders anxiety alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) depression alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) insomnia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0 0 / 103 (0.00%) 0 1 / 103 (0.97%) 1	0 / 105 (0.00%) 0 0 / 105 (0.00%) 0 1 / 105 (0.95%) 1	0 / 128 (0.00%) 0 0 / 128 (0.00%) 0 1 / 128 (0.78%) 1
Injury, poisoning and procedural complications testicular injury alternative dictionary used: MedDRA 17.0 subjects affected / exposed^[11] occurrences (all)	0 / 103 (0.00%) 0	0 / 105 (0.00%) 0	0 / 128 (0.00%) 0
Nervous system disorders			

dizziness alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	1 / 105 (0.95%) 1	0 / 128 (0.00%) 0
headache alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	3 / 105 (2.86%) 3	0 / 128 (0.00%) 0
Eye disorders dry eye alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	1 / 105 (0.95%) 1	0 / 128 (0.00%) 0
Gastrointestinal disorders abdominal pain alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 105 (0.00%) 0	0 / 128 (0.00%) 0
abdominal pain upper alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	1 / 105 (0.95%) 1	1 / 128 (0.78%) 1
constipation alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	1 / 105 (0.95%) 1	0 / 128 (0.00%) 0
diarrhoea alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 105 (0.00%) 0	0 / 128 (0.00%) 0
dyspepsia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	2 / 103 (1.94%) 5	1 / 105 (0.95%) 1	1 / 128 (0.78%) 1
gastritis			

alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 105 (0.00%) 0	0 / 128 (0.00%) 0
gastrooesophageal reflux disease alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	2 / 105 (1.90%) 2	1 / 128 (0.78%) 1
nausea alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	1 / 105 (0.95%) 1	2 / 128 (1.56%) 2
vomiting alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 105 (0.00%) 0	1 / 128 (0.78%) 1
Skin and subcutaneous tissue disorders rash alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 105 (0.00%) 0	0 / 128 (0.00%) 0
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	1 / 105 (0.95%) 1	2 / 128 (1.56%) 2
back pain alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 105 (0.00%) 0	2 / 128 (1.56%) 2
muscle spasms alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 105 (0.00%) 0	1 / 128 (0.78%) 1
musculoskeletal chest pain alternative dictionary used:			

MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences (all)	1	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	2 / 128 (1.56%)
occurrences (all)	0	0	2
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	2 / 105 (1.90%)	1 / 128 (0.78%)
occurrences (all)	0	2	1
conjunctivitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	2 / 105 (1.90%)	0 / 128 (0.00%)
occurrences (all)	0	2	0
herpes zoster			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 103 (0.97%)	2 / 105 (1.90%)	3 / 128 (2.34%)
occurrences (all)	1	2	3
influenza			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	1 / 105 (0.95%)	0 / 128 (0.00%)
occurrences (all)	1	1	0
nasopharyngitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	3 / 103 (2.91%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences (all)	3	0	1
oral candidiasis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	2 / 105 (1.90%)	0 / 128 (0.00%)
occurrences (all)	1	2	0
sinusitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	1 / 128 (0.78%)
occurrences (all)	0	0	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	3 / 103 (2.91%)	3 / 105 (2.86%)	4 / 128 (3.13%)
occurrences (all)	3	3	4
urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	6 / 103 (5.83%)	2 / 105 (1.90%)	4 / 128 (3.13%)
occurrences (all)	6	2	4
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed ^[12]	1 / 97 (1.03%)	1 / 99 (1.01%)	0 / 119 (0.00%)
occurrences (all)	1	1	0

Metabolism and nutrition disorders			
hypertriglyceridaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 103 (0.97%)	1 / 105 (0.95%)	0 / 128 (0.00%)
occurrences (all)	1	1	0
hypokalaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 103 (0.00%)	0 / 105 (0.00%)	0 / 128 (0.00%)
occurrences (all)	0	0	0

Notes:

[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.

[11] - 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.

[12] - 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? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Due to product program termination, not all analyses were completed. 2 sites were excluded from analysis due to GCP issues.

Notes: