Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of LY2127399 in Patients with Moderate to Severe Rheumatoid Arthritis (RA) who had an Inadequate Response to one or more TNF- Inhibitors (FLEX V)

Summary

EudraCT number	2010-022207-22
Trial protocol	DE ES GR IT PL
Global end of trial date	06 January 2014

Results information

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

Trial information

Trial identification

Sponsor protocol code	H9B-MC-BCDV

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01202773
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 13732

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	06 January 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 March 2013
Global end of trial reached?	Yes
Global end of trial date	06 January 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary purpose of this study is to help answer if LY2127399 is safe and effective in the treatment of rheumatoid arthritis in participants with an inadequate response to one or more tumor necrosis factor-alpha (TNF-α) inhibitors.

This study is comprised of 2 periods:

Period 1: 24-week blinded treatment

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

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 January 2011
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	48 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 268
Country: Number of subjects enrolled	Taiwan: 1
Country: Number of subjects enrolled	Greece: 4
Country: Number of subjects enrolled	Spain: 6
Country: Number of subjects enrolled	Russian Federation: 14
Country: Number of subjects enrolled	Colombia: 29
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Mexico: 8
Country: Number of subjects enrolled	Argentina: 13
Country: Number of subjects enrolled	Malaysia: 1
Country: Number of subjects enrolled	Brazil: 21
Country: Number of subjects enrolled	Poland: 42
Country: Number of subjects enrolled	Australia: 3

Country: Number of subjects enrolled	South Africa: 1
Country: Number of subjects enrolled	Germany: 10
Country: Number of subjects enrolled	New Zealand: 5
Country: Number of subjects enrolled	Japan: 18
Country: Number of subjects enrolled	Korea, Republic of: 9
Worldwide total number of subjects	456
EEA total number of subjects	65

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)	393
From 65 to 84 years	63
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Study had a treatment period (Weeks 0-24) and a post-treatment follow-up period (24-48 weeks in length). All participants were assessed for nonresponse at Week 16 with non-responders (NR) defined as participants with <20% improvement from baseline in both tender and swollen joint counts.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	120 mg LY2127399

Arm description:

A loading dose of 240 milligrams (mg) (2 injections of 120 mg) of LY2127399 followed by maintenance dosing of 120 mg of LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W) for 24 weeks. At Week 16, responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the 24-week treatment period. For blinding purposes, participants alternated injections of LY2127399 and injections of placebo every 2 weeks (Q2W).
At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 24-week treatment period.

Arm type	Experimental
Investigational medicinal product name	120 mg Tabalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

120 milligrams (mg) Tabalumab given subcutaneously (SC) every 4 weeks (Q4W) for 24 weeks. Participants receive a 240-mg loading dose when initiating treatment.

During the Treatment Period, for blinding purposes, participants will alternate injections of Tabalumab and injections of placebo every 2 weeks (Q2W).

At Week 16, responders will receive 1 injection of 120 mg of Tabalumab SC and 1 injection of placebo SC, followed by 120 mg of Tabalumab Q4W for the rest of the 24-week treatment period.

Investigational medicinal product name	90 mg Tabalumab
Investigational medicinal product code	LY2127399
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

At Week 16, non-responders (NR) will receive 1 injection of 90 mg of Tabalumab and 1 injection of placebo, followed by 90 mg of Tabalumab Q2W for the rest of the 24-week treatment period.

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

Dosage and administration details:

Placebo given SC Q2W for 24 weeks. Participants receive 2 injections of placebo when initiating treatment.

At Week 16, responders will receive 2 injections of placebo SC, followed by 1 injection of placebo SC Q2W for the rest of the 24-week treatment period.

Arm title	90 mg LY2127399

Arm description:

A loading dose of 180 mg of LY2127399 (2 injections of 90 mg) followed by maintenance dosing of 90 mg of LY2127399 administered SC Q2W for 24 weeks.
At Week 16, both responders and NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 24-week treatment period.

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

Dosage and administration details:

90 mg Tabalumab given SC Q2W for 24 weeks. Participants receive a 180-mg loading dose when initiating treatment.

At Week 16, both responders and NR will receive 1 injection of 90 mg of Tabalumab SC and 1 injection of placebo SC, followed by 90 mg of Tabalumab SC Q2W for the rest of the 24-week treatment period

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

Dosage and administration details:

At Week 16, both responders and NR received 1 injection of 90 mg of Tabalumab SC and 1 injection of placebo SC, followed by 90 mg of Tabalumab SC Q2W for the rest of the 24-week treatment period.

Arm title	Placebo

Arm description:

A loading dose of 2 injections of placebo followed by maintenance dosing of 1 injection of placebo administered SC Q2W for 24 weeks. At Week 16, responders received 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the 24-week treatment period.
At Week 16, NR received a loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by 90 mg of LY2127399 Q2W for the rest of the 24-week treatment period.

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

Dosage and administration details:

Placebo given SC Q2W for 24 weeks. Participants receive 2 injections of placebo when initiating treatment. At Week 16, responders will receive 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the 24-week treatment period.

Number of subjects in period 1	120 mg LY2127399	90 mg LY2127399	Placebo
Started	153	148	155
Received at least 1 dose of study drug	153	147	154
Week 16 NR	23 [1]	33 [2]	37 [3]
Post-Treatment Follow-Up Population	46 [4]	36 [5]	51 [6]
Completed	96	105	100
Not completed	57	43	55
Consent withdrawn by subject	13	6	5
Physician decision	2	-	-
Adverse event, non-fatal	4	5	5
Sponsor Decision	19	20	23
Lost to follow-up	1	2	2
Entry Criteria Not Met	2	-	1
Lack of efficacy	5	4	9
Protocol deviation	11	6	10

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: Participants were assessed for nonresponse at Week 16. Responders received an injection of 120mg LY2127399 and 1 injection of placebo, then followed by 120mg LY2127399 every 4 weeks for the remaining 24 week treatment period. Non-responders received 1 injection of 90 mg LY2127366 and 1 injection of placebo, then followed by 90 mg LY2127399 every 2 weeks for the remaining 24-week treatment period.

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

Justification: Participants were assessed for nonresponse at Week 16. Responders and non-responders received 1 injection of 90 mg LY2127399 and 1 injection of placebo, then followed by 90 mg LY2127399 every 2 weeks for the remaining 24-week treatment period.

[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: Participants were assessed for nonresponse at Week 16. Responders received 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the 24-week treatment period. At Week 16, non-responders received a loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by 90 mg of LY2127399 Q2W for the remaining 24-week treatment period.

[4] - 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: Participants were assessed for nonresponse at Week 16. Responders received an injection of 120mg LY2127399 and 1 injection of placebo, then followed by 120mg LY2127399 every 4 weeks for

the remaining 24 week treatment period. Non-responders received 1 injection of 90 mg LY2127366 and 1 injection of placebo, then followed by 90 mg LY2127399 every 2 weeks for the remaining 24-week treatment period.

[5] - 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: Participants were assessed for nonresponse at Week 16. Responders and non-responders received 1 injection of 90 mg LY2127399 and 1 injection of placebo, then followed by 90 mg LY2127399 every 2 weeks for the remaining 24-week treatment period.

[6] - 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: Participants were assessed for nonresponse at Week 16. Responders received 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the 24-week treatment period. At Week 16, non-responders received a loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by 90 mg of LY2127399 Q2W for the remaining 24-week treatment period.

Baseline characteristics

Reporting groups	
Reporting group title	120 mg LY2127399
Reporting group description:	
A loading dose of 240 milligrams (mg) (2 injections of 120 mg) of LY2127399 followed by maintenance dosing of 120 mg of LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W) for 24 weeks. At Week 16, responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the 24-week treatment period. For blinding purposes, participants alternated injections of LY2127399 and injections of placebo every 2 weeks (Q2W). At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 24-week treatment period.	
Reporting group title	90 mg LY2127399
Reporting group description:	
A loading dose of 180 mg of LY2127399 (2 injections of 90 mg) followed by maintenance dosing of 90 mg of LY2127399 administered SC Q2W for 24 weeks. At Week 16, both responders and NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 24-week treatment period.	
Reporting group title	Placebo
Reporting group description:	
A loading dose of 2 injections of placebo followed by maintenance dosing of 1 injection of placebo administered SC Q2W for 24 weeks. At Week 16, responders received 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the 24-week treatment period. At Week 16, NR received a loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by 90 mg of LY2127399 Q2W for the rest of the 24-week treatment period.	

Reporting group values	120 mg LY2127399	90 mg LY2127399	Placebo
Number of subjects	153	148	155
Age categorical Units: Subjects			
Gender, Male/Female Units:			
Female	124	126	131
Male	29	22	24
Region of Enrollment Units: Subjects			
United States	89	90	89
Taiwan	0	0	1
Greece	2	1	1
Spain	2	2	2
Russian Federation	6	4	4
Colombia	10	7	12
France	1	1	1
Mexico	3	3	2
Argentina	5	4	4
Malaysia	0	0	1
Brazil	7	7	7
Poland	14	14	14
Australia	0	1	2
South Africa	0	0	1
Germany	3	4	3

New Zealand	2	2	1
Japan	6	6	6
Korea, Republic of	3	2	4
Race Units: Subjects			
American Indian or Alaska Native	8	9	6
Asian	10	9	13
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	14	16	18
White	119	108	112
More than One Race	0	4	2
Unknown or Not Reported	2	2	4
Ethnicity Units: Subjects			
Hispanic or Latino	39	36	33
Not Hispanic or Latino	93	95	101
Unknown or Not Reported	21	17	21
Age Continuous Units: years			
arithmetic mean	54.2	51.3	54
standard deviation	± 11.6	± 11.7	± 11.1

Reporting group values	Total		
Number of subjects	456		
Age categorical Units: Subjects			

Gender, Male/Female Units:			
Female	381		
Male	75		
Region of Enrollment Units: Subjects			
United States	268		
Taiwan	1		
Greece	4		
Spain	6		
Russian Federation	14		
Colombia	29		
France	3		
Mexico	8		
Argentina	13		
Malaysia	1		
Brazil	21		
Poland	42		
Australia	3		
South Africa	1		
Germany	10		
New Zealand	5		
Japan	18		

Korea, Republic of	9		
Race Units: Subjects			
American Indian or Alaska Native	23		
Asian	32		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	48		
White	339		
More than One Race	6		
Unknown or Not Reported	8		
Ethnicity Units: Subjects			
Hispanic or Latino	108		
Not Hispanic or Latino	289		
Unknown or Not Reported	59		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

Reporting group title	120 mg LY2127399

Reporting group description:

A loading dose of 240 milligrams (mg) (2 injections of 120 mg) of LY2127399 followed by maintenance dosing of 120 mg of LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W) for 24 weeks.
At Week 16, responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the 24-week treatment period. For blinding purposes, participants alternated injections of LY2127399 and injections of placebo every 2 weeks (Q2W).
At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 24-week treatment period.

Reporting group title	90 mg LY2127399

Reporting group description:

A loading dose of 180 mg of LY2127399 (2 injections of 90 mg) followed by maintenance dosing of 90 mg of LY2127399 administered SC Q2W for 24 weeks.
At Week 16, both responders and NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 24-week treatment period.

Reporting group title	Placebo

Reporting group description:

A loading dose of 2 injections of placebo followed by maintenance dosing of 1 injection of placebo administered SC Q2W for 24 weeks. At Week 16, responders received 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the 24-week treatment period.
At Week 16, NR received a loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by 90 mg of LY2127399 Q2W for the rest of the 24-week treatment period.

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

Subject analysis set description:

Population estimate of constant clearance as determined by population PK analysis. A 2-compartment model was used in PK modeling. Constant clearance is the PK parameter which describes the linear elimination of LY2127399 from serum.

All randomized participants who received at least 1 dose of LY2127399 with evaluable LY2127399 PK data.

Primary: Percentage of participants with American College of Rheumatology 20% (ACR20) response

End point title	Percentage of participants with American College of Rheumatology 20% (ACR20) response[1]

End point description:

ACR Responder Index: composite of clinical, laboratory, and functional measures of rheumatoid arthritis (RA). ACR20 Responder: a ≥20% improvement from baseline in both 68 tender joint counts (TJC) and 66 swollen joint counts (SJC) and a ≥20% improvement in at least 3 of 5 criteria: participant's and physician's global assessment of disease activity, Health Assessment Questionnaire-Disability Index (HAQ-DI) (which measured participants' perceived degree of difficulty performing daily activities), joint pain, and C-reactive protein (CRP). Percentage of participants achieving ACR20 response = (number of ACR20 responders / number of participants treated) * 100. All NR at Week 16, as well as all participants who discontinued study treatment at any time for any reason, were defined as NR starting at that time-point and going forward, including Week 24 endpoint.

End point type	Primary

End point timeframe:

Baseline through Week 24

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The study was terminated early due to insufficient efficacy; statistical analysis was not conducted.

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	153	148	155	
Units: percentage of participants				
number (not applicable)	17.6	24.3	20	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point type	Secondary

End point timeframe:

Baseline through Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	153	148	155	
Units: percentage of participants				
number (not applicable)				
ACR50	7.2	5.4	3.9	
ACR70	2.6	2	0.6	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

ACR-N is a continuous measure of clinical, laboratory, and functional outcomes in RA that characterizes

percentage (%) of improvement in disease activity from baseline based on ACR core set. This index was calculated as minimum of either a) % change in TJC, b) % change in SJC, or c) the median % change of remaining 5 ACR core criteria: If ≥3 components of the 5 ACR core criteria were missing, then c) was set to missing; if any of 3 components a), b), or c) were missing, then ACR-N was set to missing. Percentage of improvement was truncated to range of -100 to 100 to minimize impact of outliers (greater values indicate greater % improvement) and negative scores indicate a decline. Least Squares (LS) means were calculated using analysis of covariance (ANCOVA) with treatment and region as fixed factors and baseline Disease Activity Score based on 28 joint counts -CRP (DAS28-CRP) as a covariate.

End point type	Secondary

End point timeframe:

Baseline through Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	153	146	153[2]	
Units: percentage of improvement				
least squares mean (standard error)	-9.03 (± 4)	-8.03 (± 4.11)	-12.72 (± 4)	

Notes:

[2] - All randomized participants with evaluable ACR-N data. Week 16 NR data were not included.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

Analysis Population Description (APD): All randomized participants with evaluable tender joint count data. Modified Baseline Observation Carried Forward (mBOCF) was used to impute missing post-baseline values. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	153	147	154	
Units: joint counts				
least squares mean (standard error)	-6.37 (± 1.4)	-6.08 (± 1.42)	-6.56 (± 1.38)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 24 in Swollen Joint Count (66 Joint Count)

End point title	Change from Baseline to Week 24 in Swollen Joint Count (66 Joint Count)

End point description:

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

Analysis Population Description: All randomized participants with evaluable swollen joint count data. mBOCF was used to impute missing post-baseline values. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	153	147	154	
Units: joint counts				
least squares mean (standard error)	-6.02 (± 0.98)	-5.64 (± 1)	-5.41 (± 0.98)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 24 in Participant's Assessment of Pain [Visual Analog Scale (VAS)]

End point title	Change from Baseline to Week 24 in Participant's Assessment of Pain [Visual Analog Scale (VAS)]

End point description:

Participant's assessment of their current arthritis pain using VAS ranged from 0 millimeters (mm) (no pain) to 100 mm (worst possible pain). A decrease in pain score indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with evaluable participant's assessment of pain data. mBOCF was used to impute missing post-baseline values. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	153	146	153	
Units: mm				
least squares mean (standard error)	-9.89 (± 2.1)	-9.15 (± 2.15)	-5.76 (± 2.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 24 in Participant’s Global Assessment of Disease Activity (VAS)

End point title	Change from Baseline to Week 24 in Participant’s Global Assessment of Disease Activity (VAS)

End point description:

Participant's assessment of their current arthritis disease activity using VAS ranged from 0 mm (no arthritis activity) to 100 mm (extremely active arthritis). A decrease in disease activity score indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with evaluable participant's global assessment of disease activity data. mBOCF was used to impute missing post-baseline values. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	153	146	153	
Units: mm				
least squares mean (standard error)	-11.29 (± 2.14)	-8.72 (± 2.19)	-7.12 (± 2.13)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 24 in Physician’s Global Assessment of Disease Activity (VAS)

End point title	Change from Baseline to Week 24 in Physician’s Global Assessment of Disease Activity (VAS)

End point description:

Physician's assessment of the participant's current arthritis disease activity using VAS ranged from 0 mm (no arthritis activity) to 100 mm (extremely active arthritis). A decrease in disease activity score indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with evaluable physician's global assessment of disease activity data. mBOCF was used to impute missing post-baseline values. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	140	150	
Units: mm				
least squares mean (standard error)	-15.9 (± 2.16)	-16.38 (± 2.23)	-13.17 (± 2.13)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

Analysis Population Description: All randomized participants with evaluable HAQ-DI data. mBOCF was used to impute missing post-baseline values. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	153	146	153	
Units: units on a scale				
least squares mean (standard error)	-0.13 (± 0.05)	-0.09 (± 0.05)	-0.08 (± 0.05)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in Disease Activity Score Based on 28 Joint Count and C-Reactive Protein Level (DAS28-CRP)

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

End point description:

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

Analysis Population Description: All randomized participants with evaluable DAS28-CRP data. mBOCF was used to impute missing post-baseline values. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	152	146	152	
Units: units on a scale				
least squares mean (standard error)	-0.76 (± 0.12)	-0.79 (± 0.13)	-0.72 (± 0.12)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

EULAR Responder index categorizes clinical response based on improvement since baseline in DAS28-CRP. DAS28-CRP=0.56*sqrt(TJC28)+0.28*sqrt(SJC28)+0.36*natural log(CRP+1)+0.014*participant global VAS+0.96. DAS28-CRP scores range from 1.0-9.4, where lower scores indicated less disease activity. High disease activity: DAS28-CRP >5.1, low disease activity: DAS28-CRP <3.2, and remission: DAS28-CRP <2.6. Participants are categorized as EULAR responders or NR based on improvement of DAS28-CRP scores from baseline. EULAR DAS28-CRP responder index defines a good (absolute: <3.2 or >1.2 improvement from baseline), moderate (absolute: 3.2-5.1 or 0.6-1.2 improvement from baseline), or no response (absolute: >5.1 or <0.6 improvement from baseline). Percentage of participants with DAS28-CRP based EULAR response = (number of participants with specific response) / (number of participants analyzed in the group) * 100.

End point type	Secondary

End point timeframe:

Baseline through Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	152[3]	146[4]	152[5]	
Units: percentage of participants				
number (not applicable)				
Good	11.8	9.6	8.6	
Moderate	36.2	36.3	36.2	
No response	52	54.1	55.3	

Notes:

[3] - All randomized participants with evaluable EULAR response data.

[4] - All randomized participants with evaluable EULAR response data.

[5] - All randomized participants with evaluable EULAR response data.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, 2 component scores (CS), physical CS (PCS) and mental CS (MCS). Domain scores calculated by summing each item for each domain and transforming scores into 0-100 scale; higher scores indicated better health status. If < 50% of the questions within a domain were answered, the raw score was not calculated. PCS score consisted of physical functioning, bodily pain, role-physical, and general health scales. MCS score consisted of social functioning, vitality, mental health, and role-emotional scales. Both PCS and MCS range from 0-100 with higher score indicating better mental or physical health. LS means were calculated using ANCOVA with treatment, region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146[6]	138[7]	149[8]	
Units: units on a scale				
least squares mean (standard error)				
Physical Functioning	1.81 (± 0.78)	1.78 (± 0.82)	1 (± 0.77)	
Bodily Pain	2.36 (± 0.75)	2.95 (± 0.78)	1.97 (± 0.74)	
Role Limitations Due to Physical Problems	1.92 (± 0.72)	2.08 (± 0.75)	0.35 (± 0.72)	
Role Limitations Due to Emotional Problems	1.07 (± 0.97)	2.55 (± 1.01)	1.19 (± 0.96)	
General Health Perception	1.9 (± 0.64)	0.91 (± 0.67)	1.88 (± 0.64)	
Mental Health	0.83 (± 0.85)	1.57 (± 0.88)	0.98 (± 0.84)	
Social Function	2.51 (± 0.87)	1.68 (± 0.91)	1.32 (± 0.86)	
Vitality	2.71 (± 0.77)	2.4 (± 0.8)	2.05 (± 0.76)	
PCS	2.3 (± 0.71)	1.83 (± 0.74)	1.21 (± 0.71)	
MCS	1.22 (± 0.87)	1.86 (± 0.9)	1.38 (± 0.86)	

Notes:

[6] - All randomized participants with evaluable SF-36 domain and summary scores.

[7] - All randomized participants with evaluable SF-36 domain and summary scores.

[8] - All randomized participants with evaluable SF-36 domain and summary scores.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 24 in Brief Fatigue Inventory (BFI) Individual Items and Impact Scores

End point title	Change from Baseline to Week 24 in Brief Fatigue Inventory (BFI) Individual Items and Impact Scores

End point description:

The BFI is a brief participant-reported questionnaire for the rapid assessment of fatigue severity and the impact of fatigue on daily functioning in the past 24 hours. The BFI contains 10 items; however, the first item is not included in the scoring of the scale as it asks about usual fatigue over the past week with the participant answering 'yes' or 'no'. The remaining 9 items assess fatigue severity (3 items) and impact of fatigue on daily functioning (6 items) using an 11-point numeric scale, with 0 = no fatigue and 10 = fatigue as bad as you can imagine. The fatigue impact subscale score is the average of the non-missing responses to 6 items: general activity, mood, walking ability, normal work, relations with other people, and enjoyment of life. If more than 3 items within the fatigue impact subscale were not answered by a participant, the subscale is set to missing. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146[9]	138[10]	149[11]	
Units: units on a scale				
least squares mean (standard error)				
Fatigue - Now	-0.68 (± 0.12)	-0.55 (± 0.12)	-0.6 (± 0.12)	
Fatigue - Usual	-0.65 (± 0.11)	-0.58 (± 0.11)	-0.56 (± 0.11)	
Fatigue – Worst	-0.75 (± 0.12)	-0.65 (± 0.12)	-0.72 (± 0.12)	
General Activity	-0.55 (± 0.12)	-0.5 (± 0.12)	-0.52 (± 0.12)	
Mood	-0.54 (± 0.12)	-0.35 (± 0.12)	-0.35 (± 0.12)	
Walking Ability	-0.53 (± 0.12)	-0.38 (± 0.13)	-0.36 (± 0.12)	
Normal Work	-0.6 (± 0.12)	-0.46 (± 0.12)	-0.42 (± 0.12)	
Relations with Other People	-0.41 (± 0.12)	-0.43 (± 0.12)	-0.29 (± 0.12)	
Enjoyment of Life	-0.53 (± 0.13)	-0.55 (± 0.13)	-0.41 (± 0.13)	
Fatigue Impact Subscale	-0.52 (± 0.11)	-0.43 (± 0.11)	-0.39 (± 0.11)	

Notes:

[9] - All randomized participants with evaluable BFI data.

[10] - All randomized participants with evaluable BFI data.

[11] - All randomized participants with evaluable BFI data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 24 in Brief Pain Inventory Short Form (BPI-SF) Individual Items and Interference Scores

End point title	Change from Baseline to Week 24 in Brief Pain Inventory Short Form (BPI-SF) Individual Items and Interference Scores

End point description:

The BPI-SF is a self-reported scale that measures the severity of pain based on the worst pain, least pain, average pain experienced during the past 24 hours and pain based on the pain right now, with scores ranging from 0 (no pain) to 10 (pain as severe as you can imagine). Pain interference score is the average of the responses in the past 24 hours to 7 items: general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life [each item scored from 0 (does not interfere) to 10 (completely interferes)]. If more than 3 items of the Pain Interference Score are not answered by a participant, the score is set to missing. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with evaluable BPI-SF scores. mBOCF was used to impute missing post-baseline values. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	138	149	
Units: units on a scale				
least squares mean (standard error)				
Pain - Worst (n=146, 138, 149)	-0.9 (± 0.2)	-0.8 (± 0.2)	-0.4 (± 0.2)	
Pain - Least (n=146, 138, 149)	-0.5 (± 0.2)	-0.5 (± 0.2)	-0.1 (± 0.2)	

Pain - Average (n=146, 138, 149)	-0.7 (± 0.2)	-0.7 (± 0.2)	-0.3 (± 0.2)	
Pain - Now (n=146, 137, 149)	-0.8 (± 0.2)	-0.5 (± 0.2)	-0.3 (± 0.2)	
General Activity (n=146, 137, 149)	-0.7 (± 0.2)	-0.4 (± 0.2)	-0.3 (± 0.2)	
Mood (n=146, 137, 149)	-0.6 (± 0.2)	-0.2 (± 0.2)	0 (± 0.2)	
Walking Ability (n=146, 137, 149)	-0.8 (± 0.2)	-0.4 (± 0.2)	-0.4 (± 0.2)	
Normal Work (n=146, 137, 149)	-0.7 (± 0.2)	-0.4 (± 0.2)	-0.2 (± 0.2)	
Relations with Other People (n=146, 137, 149)	-0.3 (± 0.2)	-0.2 (± 0.2)	-0.1 (± 0.2)	
Sleep (n=146, 137, 149)	-0.7 (± 0.2)	-0.3 (± 0.2)	-0.4 (± 0.2)	
Enjoyment of Life (n=146, 137, 149)	-0.7 (± 0.2)	-0.4 (± 0.2)	-0.4 (± 0.2)	
Pain Interference Score (n=146, 137, 149)	-0.6 (± 0.2)	-0.3 (± 0.2)	-0.3 (± 0.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in Duration of Morning Stiffness (Minutes)

End point title	Change From Baseline to Week 24 in Duration of Morning Stiffness (Minutes)

End point description:

The Investigator asks participants about the duration of their morning stiffness (in minutes) in and around the joints and records the duration. The Investigator should ask participants about duration of morning stiffness on the day prior to the study visit to capture actual symptoms. If morning stiffness duration is longer than 12 hours (720 minutes), it was truncated to 720 minutes for statistical presentations and analyses.LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with evaluable morning stiffness data; mBOCF was used to impute missing post-baseline values. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	141	138	139	
Units: minutes				
least squares mean (standard error)	-20.6 (± 11.5)	-1 (± 11.7)	-18 (± 11.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to ACR20 response

End point title	Time to ACR20 response

End point description:

End point type	Secondary

End point timeframe:

Baseline through Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[12]	0[13]	0[14]	
Units: participants				
number (not applicable)				

Notes:

[12] - Zero participants were analyzed because of the limited efficacy of Tabalumab in the treatment of RA.
[13] - Zero participants were analyzed because of the limited efficacy of Tabalumab in the treatment of RA.
[14] - Zero participants were analyzed because of the limited efficacy of Tabalumab in the treatment of RA.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in Absolute B Cell Counts

End point title	Change From Baseline to Week 24 in Absolute B Cell Counts

End point description:

Cell-surface marker cluster designation (CD) 3 negative, CD20 positive (CD3-CD20+) defines total mature B cells. B-lymphocyte antigen CD20 is an activated-glycosylated phosphoprotein expressed on the surface of all mature B cells. Baseline B cell count is the average of the values on or prior to the date of first injection of study treatment, including unscheduled visits. A positive or negative change indicated an increase or decrease, respectively in B cell count. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with evaluable CD3-CD20+ B cell counts. mLOCF was used to impute missing post-baseline values. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	151	147	155	
Units: cells/microliter (cells/µL)				
least squares mean (standard error)	-55.3 (± 9.9)	-65.8 (± 10.1)	3.2 (± 9.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in Serum Immunoglobulin (Ig) Levels

End point title	Change From Baseline to Week 24 in Serum Immunoglobulin (Ig) Levels

End point description:

Immunoglobulin (Ig), or antibodies, are large proteins used by the immune system to identify and neutralize foreign particles such as bacteria and viruses. Their normal blood levels indicate proper immune status. Change from baseline in serum immunoglobulin A (IgA), immunoglobulin G (IgG), and immunoglobulin M (IgM) levels are reported. A negative change indicated a decrease in Ig levels. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with evaluable serum Ig data. mLOCF was used to impute missing post-baseline values. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	151	146	153	
Units: grams/liter (g/L)				
least squares mean (standard error)				
IgA	-0.33 (± 0.049)	-0.324 (± 0.05)	0.003 (± 0.049)	
IgG	-0.955 (± 0.161)	-0.978 (± 0.163)	0.058 (± 0.158)	
IgM	-0.273 (± 0.043)	-0.239 (± 0.044)	-0.019 (± 0.042)	

Statistical analyses

No statistical analyses for this end point

Secondary: Population Pharmacokinetics (PK): Constant Clearance

End point title	Population Pharmacokinetics (PK): Constant Clearance

End point description:

Population estimate of constant clearance as determined by population PK analysis. A 2-compartment model was used in PK modeling. Constant clearance is the PK parameter which describes the linear elimination of LY2127399 from serum.

Analysis Population Description: All randomized participants who received at least 1 dose of LY2127399 with evaluable LY2127399 PK data.

End point type	Secondary

End point timeframe:

Baseline through Week 24

End point values	Population Pharmacokinetics (PK): Constant Clearance			
Subject group type	Subject analysis set			
Number of subjects analysed	309			
Units: milliliters/hour (mL/h)				
arithmetic mean (standard error)	4.16 (± 3.58)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Developing Anti-LY2127399 Antibodies

End point title	Percentage of Participants Developing Anti-LY2127399 Antibodies

End point description:

Participants with treatment-emergent anti-drug antibody (ADA) were participants who had any sample from baseline up to and through Week 52 that was a 4-fold increase (2-dilution increase) in immunogenicity titer over baseline titer, or participants who tested negative at baseline and positive post-baseline (at titer of ≥1:20). Percentage of participants with ADA = (number of participants with treatment-emergent ADA) / (number of participants assessed) * 100.

Analysis Population Description: All randomized participants who received at least 1 dose of study drug with an evaluable baseline ADA result and a post-baseline ADA result. Participants missing an evaluable baseline result with all negative post-baseline results were included. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline through Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	153	147	154	
Units: percentage of participants				
number (not applicable)	3.9	4.8	3.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 24 in CRP

End point title	Change from Baseline to Week 24 in CRP

End point description:

CRP is an indicator of inflammation. A negative change indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

Analysis Population Description: All randomized participants with evaluable CRP data. mBOCF was used to impute missing post-baseline values. Data after Week 16 for Week 16 NR were not included.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	152	147	154	
Units: milligrams/liter (mg/L)				
least squares mean (standard error)	2.91 (± 1.83)	0.95 (± 1.87)	2.93 (± 1.81)	

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-BCDV	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups	
Reporting group title	LY 120 mg Q4W, Randomized Treatment Period
Reporting group description: -	
Reporting group title	LY 90 mg Q2W, Randomized Treatment Period
Reporting group description: -	
Reporting group title	Placebo, Randomized Treatment Period
Reporting group description: -	
Reporting group title	LY 120 mg Q4W, Rescue Period
Reporting group description: -	
Reporting group title	LY 90 mg Q2W, Rescue Period
Reporting group description: -	
Reporting group title	Placebo, Rescue Period
Reporting group description: -	
Reporting group title	LY 120 mg Q4W, Follow-up Period
Reporting group description: -	
Reporting group title	LY 90 mg Q2W, Follow-up Period
Reporting group description: -	
Reporting group title	Placebo, Follow-up Period
Reporting group description: -	
Reporting group title	LY 120 mg Q4W to LY 90 mg Q2W (Week 16), Follow-up Period
Reporting group description: -	
Reporting group title	Placebo to LY 90 mg Q2W (Week 16), Follow-up Period
Reporting group description: -	

Serious adverse events	LY 120 mg Q4W, Randomized Treatment Period	LY 90 mg Q2W, Randomized Treatment Period	Placebo, Randomized Treatment Period
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 153 (4.58%)	6 / 147 (4.08%)	6 / 154 (3.90%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma gastric			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
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 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (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
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (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			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (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			
alcohol abuse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
somatoform disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (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
Injury, poisoning and procedural complications			
femoral neck fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
jaw fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (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
procedural pain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
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			
coronary artery stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (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
iron deficiency anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
meniere's disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (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
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (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
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
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 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (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
lumbar spinal stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
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 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 153 (1.31%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rotator cuff syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (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
synovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (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			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 153 (1.31%)	0 / 147 (0.00%)	0 / 154 (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
pyomyositis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	LY 120 mg Q4W, Rescue Period	LY 90 mg Q2W, Rescue Period	Placebo, Rescue Period
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 23 (4.35%)	2 / 33 (6.06%)	1 / 37 (2.70%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma gastric			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	0 / 33 (0.00%)	0 / 37 (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
pulmonary embolism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
alcohol abuse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
somatoform disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
femoral neck fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
jaw fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
procedural pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
coronary artery stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
iron deficiency anaemia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
meniere's disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar spinal stenosis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rotator cuff syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyomyositis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	LY 120 mg Q4W, Follow-up Period	LY 90 mg Q2W, Follow-up Period	Placebo, Follow-up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 43 (2.33%)	1 / 36 (2.78%)	3 / 44 (6.82%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma gastric			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
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 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypotension			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
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			
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (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			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
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			
alcohol abuse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
somatoform disorder			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
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			
femoral neck fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
jaw fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
procedural pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (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 disorders			
coronary artery stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (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
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
iron deficiency anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 43 (2.33%)	0 / 36 (0.00%)	0 / 44 (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
Ear and labyrinth disorders			
meniere's disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
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 pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
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			
arthritis			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
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 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar spinal stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rotator cuff syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
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			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyomyositis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	LY 120 mg Q4W to LY 90 mg Q2W (Week 16), Follow-up Period	Placebo to LY 90 mg Q2W (Week 16), Follow-up Period	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma gastric			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumothorax			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary embolism			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
alcohol abuse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
somatoform disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
femoral neck fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
femur fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
jaw fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
procedural pain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
coronary artery stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myocardial infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
iron deficiency anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
meniere's disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
retinal detachment			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc protrusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lumbar spinal stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rotator cuff syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
synovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
device related infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyomyositis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	LY 120 mg Q4W, Randomized Treatment Period	LY 90 mg Q2W, Randomized Treatment Period	Placebo, Randomized Treatment Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	71 / 153 (46.41%)	51 / 147 (34.69%)	61 / 154 (39.61%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
dysplastic naevus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
melanocytic naevus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
neoplasm prostate			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[1]	1 / 29 (3.45%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 153 (1.31%)	1 / 147 (0.68%)	4 / 154 (2.60%)
occurrences (all)	2	1	4
hypertensive crisis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

asthenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	1	0	0
chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	1	0	0
chills			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences (all)	1	0	1
injection site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	3 / 147 (2.04%)	1 / 154 (0.65%)
occurrences (all)	2	3	1
injection site pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 153 (1.31%)	5 / 147 (3.40%)	4 / 154 (2.60%)
occurrences (all)	6	18	21
injection site reaction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 153 (2.61%)	7 / 147 (4.76%)	0 / 154 (0.00%)
occurrences (all)	6	19	0
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	4 / 147 (2.72%)	2 / 154 (1.30%)
occurrences (all)	0	4	3
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	1 / 147 (0.68%)	2 / 154 (1.30%)
occurrences (all)	1	1	3
Immune system disorders			

seasonal allergy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[2]	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
allergic cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	1	0	0
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 153 (1.96%)	1 / 147 (0.68%)	3 / 154 (1.95%)
occurrences (all)	3	1	3
Psychiatric disorders			
depressed mood			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 153 (1.31%)	0 / 147 (0.00%)	4 / 154 (2.60%)
occurrences (all)	2	0	4
Investigations			
haemoglobin decreased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	1	0	0
lipase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
neutrophil count increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	1	0	0
weight decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
white blood cell count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
hand fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	1	0	0
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	1	0	0
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (0.00%)
occurrences (all)	0	1	0
spinal compression fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	0	1
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 153 (1.96%)	1 / 147 (0.68%)	2 / 154 (1.30%)
occurrences (all)	3	1	2
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 153 (4.58%)	2 / 147 (1.36%)	5 / 154 (3.25%)
occurrences (all)	8	2	5
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	2 / 154 (1.30%)
occurrences (all)	0	0	2
leukopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	1	0	0
vertigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	1 / 147 (0.68%)	1 / 154 (0.65%)
occurrences (all)	1	1	1
diarrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 153 (1.31%)	2 / 147 (1.36%)	3 / 154 (1.95%)
occurrences (all)	2	2	3
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 153 (3.92%)	1 / 147 (0.68%)	2 / 154 (1.30%)
occurrences (all)	6	1	2
oedema mouth			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 153 (1.96%)	1 / 147 (0.68%)	1 / 154 (0.65%)
occurrences (all)	3	1	1
Hepatobiliary disorders			
liver disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
blister			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (0.00%)
occurrences (all)	0	1	0
dry skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 153 (2.61%)	1 / 147 (0.68%)	0 / 154 (0.00%)
occurrences (all)	4	1	0
pain of skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
rash macular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			

arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 153 (1.96%)	3 / 147 (2.04%)	2 / 154 (1.30%)
occurrences (all)	3	3	2
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 153 (1.31%)	2 / 147 (1.36%)	2 / 154 (1.30%)
occurrences (all)	2	2	2
myalgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	1	0	0
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	1 / 147 (0.68%)	1 / 154 (0.65%)
occurrences (all)	1	1	1
osteoporosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences (all)	1	0	1
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	4 / 154 (2.60%)
occurrences (all)	1	0	5
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 153 (5.23%)	7 / 147 (4.76%)	11 / 154 (7.14%)
occurrences (all)	9	7	13
spinal osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	0	1
synovial cyst			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 153 (0.65%)	1 / 147 (0.68%)	2 / 154 (1.30%)
occurrences (all)	1	1	2
tendonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 153 (1.31%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
adenoiditis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
alveolar osteitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
bacterial infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 153 (1.31%)	3 / 147 (2.04%)	3 / 154 (1.95%)
occurrences (all)	2	3	3
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences (all)	1	0	1
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	1 / 154 (0.65%)
occurrences (all)	0	1	1
gastroenteritis viral			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	1 / 154 (0.65%)
occurrences (all)	0	1	1
herpes simplex			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 153 (1.31%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences (all)	2	0	1
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	3 / 147 (2.04%)	2 / 154 (1.30%)
occurrences (all)	1	3	2
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 153 (2.61%)	2 / 147 (1.36%)	0 / 154 (0.00%)
occurrences (all)	4	2	0
pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	0	1
respiratory tract infection viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 153 (3.27%)	2 / 147 (1.36%)	7 / 154 (4.55%)
occurrences (all)	6	2	7
staphylococcal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0

subcutaneous abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	0	1
tooth infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	1 / 154 (0.65%)
occurrences (all)	0	1	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	9 / 153 (5.88%)	7 / 147 (4.76%)	9 / 154 (5.84%)
occurrences (all)	10	7	11
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 153 (3.27%)	6 / 147 (4.08%)	2 / 154 (1.30%)
occurrences (all)	5	6	2
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 153 (0.65%)	0 / 147 (0.00%)	2 / 154 (1.30%)
occurrences (all)	1	0	2
gout			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 153 (0.00%)	1 / 147 (0.68%)	0 / 154 (0.00%)
occurrences (all)	0	1	0
vitamin d deficiency			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 153 (0.00%)	0 / 147 (0.00%)	0 / 154 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	LY 120 mg Q4W, Rescue Period	LY 90 mg Q2W, Rescue Period	Placebo, Rescue Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 23 (43.48%)	11 / 33 (33.33%)	16 / 37 (43.24%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
dysplastic naevus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
melanocytic naevus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
neoplasm prostate			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[1]	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
hypertensive crisis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
chest pain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
chills			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	2
injection site reaction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	3 / 37 (8.11%)
occurrences (all)	0	0	10
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
seasonal allergy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed[2]	1 / 19 (5.26%)	0 / 28 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
allergic cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
depressed mood			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Investigations			
haemoglobin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
lipase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
neutrophil count increased			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
white blood cell count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
hand fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
procedural pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
spinal compression fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
leukopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
oedema mouth			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
liver disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
blister			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
dry skin			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
pain of skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
rash macular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
myalgia			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
osteoporosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	0 / 33 (0.00%)	2 / 37 (5.41%)
occurrences (all)	1	0	2
spinal osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
synovial cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
tendonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
adenoiditis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
alveolar osteitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
bacterial infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
gastroenteritis viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
herpes simplex			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	1 / 37 (2.70%)
occurrences (all)	0	1	1

influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
respiratory tract infection viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
staphylococcal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 23 (4.35%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	1 / 33 (3.03%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
gout			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 23 (0.00%)	0 / 33 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	LY 120 mg Q4W, Follow-up Period	LY 90 mg Q2W, Follow-up Period	Placebo, Follow-up Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 43 (13.95%)	11 / 36 (30.56%)	14 / 44 (31.82%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
dysplastic naevus			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
melanocytic naevus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
neoplasm prostate			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[1]	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
hypertensive crisis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
chills			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 43 (2.33%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	1	0	0
injection site erythema			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
seasonal allergy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[2]	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
allergic cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
chronic obstructive pulmonary disease			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 43 (2.33%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	1	0	0
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
depressed mood			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
Investigations			
haemoglobin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
lipase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
neutrophil count increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 43 (2.33%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	1	0	0
weight decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
white blood cell count decreased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 43 (2.33%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	1	0	0
white blood cell count increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 43 (2.33%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
hand fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 43 (4.65%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	2	0	0
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
spinal compression fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 43 (2.33%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 43 (2.33%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	1	0	1
leukopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	1 / 44 (2.27%)
occurrences (all)	0	1	1
lymphopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
vertigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	1 / 44 (2.27%)
occurrences (all)	0	1	1
diarrhoea			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
oedema mouth			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
liver disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
blister			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
dry skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
pain of skin			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
rash macular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
urticaria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 43 (2.33%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	1	0	3
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 43 (2.33%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	1	1	0
osteoporosis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 43 (0.00%)	2 / 36 (5.56%)	0 / 44 (0.00%)
occurrences (all)	0	2	0
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	2
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	2 / 36 (5.56%)	2 / 44 (4.55%)
occurrences (all)	0	2	2
spinal osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
synovial cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
adenoiditis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
alveolar osteitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
bacterial infection			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
gastroenteritis viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
herpes simplex			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 43 (2.33%)	1 / 36 (2.78%)	1 / 44 (2.27%)
occurrences (all)	1	1	1

pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
respiratory tract infection viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	3 / 44 (6.82%)
occurrences (all)	0	0	3
staphylococcal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
subcutaneous abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
tooth abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
tooth infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	2 / 36 (5.56%)	0 / 44 (0.00%)
occurrences (all)	0	2	0
urinary tract infection			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	1 / 36 (2.78%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
gout			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 43 (0.00%)	0 / 36 (0.00%)	1 / 44 (2.27%)
occurrences (all)	0	0	1
vitamin d deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 43 (2.33%)	0 / 36 (0.00%)	0 / 44 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	LY 120 mg Q4W to LY 90 mg Q2W (Week 16), Follow-up Period	Placebo to LY 90 mg Q2W (Week 16), Follow-up Period	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
dysplastic naevus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
melanocytic naevus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
neoplasm prostate			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed[1]	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
hypertensive crisis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
chills			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
injection site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
injection site pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
injection site reaction			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
seasonal allergy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[2]	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
allergic cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			

depressed mood			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Investigations			
haemoglobin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
lipase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
neutrophil count increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
weight decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
white blood cell count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
white blood cell count increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			

hand fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
procedural pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
spinal compression fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
leukopenia			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
lymphopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
vertigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
diarrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
oedema mouth			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
liver disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
blister			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
dry skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
hyperhidrosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
pain of skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
rash macular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
urticaria			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
myalgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
osteoporosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
spinal osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
synovial cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
tendonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
adenoiditis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
alveolar osteitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
bacterial infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
cellulitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)		
occurrences (all)	0	0		
gastroenteritis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)		
occurrences (all)	0	0		
gastroenteritis viral				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)		
occurrences (all)	0	0		
herpes simplex				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)		
occurrences (all)	0	0		
herpes zoster				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)		
occurrences (all)	0	0		
influenza				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)		
occurrences (all)	0	0		
nasopharyngitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)		
occurrences (all)	0	0		
pharyngitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)		
occurrences (all)	0	0		
respiratory tract infection viral				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)		
occurrences (all)	0	0		

sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
staphylococcal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
subcutaneous abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
tooth abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
tooth infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
gout			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	
vitamin d deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	
occurrences (all)	0	0	

Notes:

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 May 2011	Amendment A Added Columbia-Suicide Severity Rating Scale (C-SSRS) for prospective assessment of the occurrence of treatment-emergent suicidality, including addition of: o Statistical methodology for analyses of responses o Exclusion criterion of recent suicidal ideation or behavior o Language for discontinuation of study drug should a patient develop a significant uncontrolled medical condition, such as a neuropsychiatric disorder that in the opinion of the Investigator after appropriate medical assessment, would pose an unacceptable risk to the patient if the patient were to continue receiving study drug. In compliance with changes to in United States of America, 21 Code of Federal Regulation (CFR) Parts 312 and 320: o Added information on reasonably anticipated adverse events also being available in the compound Investigator's Brochure. o Added a summary of reasonably anticipated serious adverse events for the RA population under study. o Added language that the Sponsor may review unblinded safety data in the event that it would be required for evaluation of selected SAEs to aide in determination of regulatory reporting. Also clarified that DMC may not be the only committee to review unblinded safety data to accommodate the statement immediately preceding this one. Added text clarifying that at least four criteria must be fulfilled for classification of RA to Appendix 4. Appendix 4 is the American Rheumatism Association 1987 Revised Criteria for the Classification of RA referenced in inclusion criterion #2 as the criteria for the diagnosis of adult-onset RA. Modified existing exclusion criteria: o #4 to address biologic DMARD washout periods as DMARDs may interfere with interpretation of efficacy results. o #11 to include the C-SSRS. o #15 to clarify what constitutes HCV positive status. Clarified the standardized sequence of assessments that contribute to blinding being maintained in the
17 May 2011	Amendment A Continued: Concomitant Medications were updated to clarify language associated with NSAIDs and analgesics and to add text regarding proton pump inhibitors and H2 receptor blockers. Clarified the definition of the treatment-adverse events. Statistical Methodology changes: o Correcting the significance level for interaction effects from 0.010 to 0.10. o Modification of the text for non-responder imputation for clinical response (ACR20/50/70).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

This study has been terminated not based on safety concerns, but due to insufficient efficacy. Early termination led to lower than expected enrollment and was responsible for the large number of discontinuation reason as Sponsor Decision.

Notes: