Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Parallel-Group, Phase 2b Study of LY3009104 in Patients with Active Rheumatoid Arthritis on Background Methotrexate Therapy

Summary

EudraCT number	2010-022504-42
Trial protocol	GB HU
Global end of trial date	31 March 2014

Results information

Result version number	v2 (current)
This version publication date	14 October 2017
First version publication date	26 March 2017
Version creation reason	• Correction of full data set Revision Required

Trial information

Trial identification

Sponsor protocol code	13854

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01185353
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Alias: I4V-MC-JADA, Trial ID: 13854

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, 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	31 March 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 March 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this trial is to evaluate the safety and efficacy of LY3009104 in participants with Rheumatoid Arthritis (RA).

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:

Methotrexate (MTX) was administered orally as background therapy. Participants must have regularly used methotrexate (MTX) for at least 12 weeks, with treatment at a stable dose of 10 to 25 milligrams (mg) per week for at least 8 weeks prior to baseline.

Evidence for comparator: -

Actual start date of recruitment	13 October 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 95
Country: Number of subjects enrolled	Hungary: 13
Country: Number of subjects enrolled	Czech Republic: 23
Country: Number of subjects enrolled	Mexico: 47
Country: Number of subjects enrolled	Poland: 33
Country: Number of subjects enrolled	Ukraine: 29
Country: Number of subjects enrolled	Croatia: 7
Country: Number of subjects enrolled	Romania: 11
Country: Number of subjects enrolled	India: 43
Worldwide total number of subjects	301
EEA total number of subjects	87

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	263
From 65 to 84 years	38
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study consisted of 4 parts and a follow-up up to 28 days post the last dose of study drug.

Period 1

Period 1 title	Part A (Weeks 0 through 12)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	1 milligram (mg) LY3009104 QD - Part A

Arm description:

Administered orally once daily (QD) for 12 weeks in Part A.

Methotrexate (MTX) was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

1mg LY3009104 once daily for 12 weeks in Part A

Arm title	2 mg LY3009104 QD - Parts A and B

Arm description:

Administered orally QD for 24 weeks in Parts A and B.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

2 mg LY3009104 once daily for 24 weeks in Parts A and B

Arm title	4 mg LY3009104 QD - Parts A and B

Arm description:

Administered orally QD for 24 weeks in Parts A and B.

MTX was administered orally as background therapy.

Arm type	Experimental

Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4 mg LY3009104 once daily for 24 weeks in Parts A and B

Arm title	8 mg LY3009104 QD - Parts A and B

Arm description:

Administered orally QD for 24 weeks in Parts A and B.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

8 mg LY3009104 once daily for 24 weeks in Parts A and B

Arm title	Placebo QD - Part A

Arm description:

Placebo administered orally QD for 12 weeks in Part A.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo daily for 12 weeks

Number of subjects in period 1	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B
Started	49	52	52
Received at least 1 dose of study drug	49	52	52
Completed	44	51	50
Not completed	5	1	2
Consent withdrawn by subject	2	-	-
Physician decision	-	-	1
Adverse event, non-fatal	1	1	1
Entry Criteria Not Met	-	-	-
Lack of efficacy	2	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	8 mg LY3009104 QD - Parts A and B	Placebo QD - Part A
Started	50	98
Received at least 1 dose of study drug	50	98
Completed	49	82
Not completed	1	16
Consent withdrawn by subject	-	3
Physician decision	-	2
Adverse event, non-fatal	1	5
Entry Criteria Not Met	-	4
Lack of efficacy	-	1
Protocol deviation	-	1

Period 2

Period 2 title	Part B (Weeks 12 through 24)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	2 mg LY3009104 QD - Parts A and B

Arm description:

Administered orally QD for 24 weeks in Parts A and B.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

2 mg LY3009104 once daily for 24 weeks in Parts A and B

Arm title	4 mg LY3009104 QD - Parts A and B

Arm description:

Administered orally QD for 24 weeks in Parts A and B.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4 mg LY3009104 once daily for 24 weeks in Parts A and B

Arm title	8 mg LY3009104 QD - Parts A and B

Arm description:

Administered orally QD for 24 weeks in Parts A and B.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

8 mg LY3009104 once daily for 24 weeks in Parts A and B

Arm title	2 mg LY3009104 BID - Part B

Arm description:

Participants who received Placebo or 1 mg LY3009104 in Part A were re-randomized at Week 12 to receive 2 mg LY3009104 twice daily (BID) in Part B.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

2 mg LY3009104 twice daily for 12 weeks in Part B

Arm title	4 mg LY3009104 QD - Part B

Arm description:

Participants who received Placebo or 1 mg LY3009104 in Part A were re-randomized at Week 12 to receive 4 mg LY3009104 QD in Part B.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4 mg LY3009104 once daily for 12 weeks in Part B

Number of subjects in period 2	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Started	51	50	49
Completed	50	48	45
Not completed	1	2	4
Consent withdrawn by subject	-	1	2
Adverse event, non-fatal	-	1	-
Lost to follow-up	-	-	1
Entry Criteria Not Met	-	-	-
Lack of efficacy	1	-	1

Number of subjects in period 2	2 mg LY3009104 BID - Part B	4 mg LY3009104 QD - Part B
Started	63	63
Completed	59	57
Not completed	4	6
Consent withdrawn by subject	3	4
Adverse event, non-fatal	1	-
Lost to follow-up	-	1
Entry Criteria Not Met	-	1
Lack of efficacy	-	-

Period 3	
Period 3 title	Part C (Weeks 24 through 76)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	4 mg LY3009104 QD - Parts C and D

Arm description:

Participants who received 2 mg LY3009104 QD or BID in Part B were re-assigned at Week 24 to 4 mg LY3009104 QD in Part C.

Participants who received 4 mg LY3009104 QD in Part B continued to receive 4 mg LY3009104 QD in Part C.

Participants who completed Part C continued to receive 4 mg LY3009104 QD in Part D.

MTX was administered orally as background therapy.

Arm type	Experimental

Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4 mg LY3009104 once daily for 52 weeks in Part C

Arm title	4 to 8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D

Arm description:

Participants who received 2 mg LY3009104 QD or BID in Part B were re-assigned at Week 24 to 4 mg LY3009104 QD in Part C.

Participants who received 4 mg LY3009104 QD in Part B continued to receive 4 mg LY3009104 QD in Part C.

At Weeks 28 and 32, participants who met dose escalation criteria received 8 mg LY3009104 QD for the rest of Part C.

Dose escalation criteria: ≥ 6 tender and 6 swollen joints based on the 28-joint count assessments and the clinical judgment of the investigator.

Participants who completed Part C received 4 mg LY3009104 QD in Part D.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4mg escalated to 8 mg LY3009104 once daily for 52 weeks in Part C

Arm title	8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D

Arm description:

Participants who received 8 mg LY3009104 QD in Part B remained on 8 mg LY3009104 QD in Part C.

Participants who completed Part C received 4 mg LY3009104 QD in Part D.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

8 mg LY3009104 once daily for 52 weeks in Part C

Number of subjects in period 3[1]	4 mg LY3009104 QD - Parts C and D	4 to 8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D	8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D
Started	108	61	32
Completed	92	53	24
Not completed	16	8	8
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	6	2	2
Physician decision	-	-	1
Adverse event, non-fatal	8	2	2
Lost to follow-up	2	1	1
Entry Criteria Not Met	-	-	1
Reason missing	-	1	-
Lack of efficacy	-	2	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Participants who received 2mg LY3009104 QD or BID in Part B were reassigned at Wk 24 to receive 4 mg LY3009104 in Part C. Participants who received 4mg LY3009104 in Part B continued to received 4mg LY3009104 in Part C. At Wk 28 participants were assessed for dose escalation to receive 8 mg LY3009104 QD for the remainder of Part C. Participants who received 8 mg LY3009104 QD in Part B remained on 8 mg LY3009104 QD in Part C.

Period 4

Period 4 title	Part D (Weeks 76 through 128)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	4 mg LY3009104 QD - Parts C and D

Arm description:

Participants who received 2 mg LY3009104 QD or BID in Part B were re-assigned at Week 24 to 4 mg LY3009104 QD in Part C.

Participants who received 4 mg LY3009104 QD in Part B continued to receive 4 mg LY3009104 QD in Part C.

Participants who completed Part C continued to receive 4 mg LY3009104 QD in Part D.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4 mg LY3009104 once daily for 52 weeks in Part D

Arm title	4 to 8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D

Arm description:

Participants who received 2 mg LY3009104 QD or BID in Part B were re-assigned at Week 24 to 4 mg LY3009104 QD in Part C.

Participants who received 4 mg LY3009104 QD in Part B continued to receive 4 mg LY3009104 QD in Part C.

At Weeks 28 and 32, participants who met dose escalation criteria received 8 mg LY3009104 QD for the rest of Part C.

Dose escalation criteria: ≥ 6 tender and 6 swollen joints based on the 28-joint count assessments and the clinical judgment of the investigator.

Participants who completed Part C received 4 mg LY3009104 QD in Part D.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4 mg LY3009104 once daily for 52 weeks in Part D

Arm title	8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D

Arm description:

Participants who received 8 mg LY3009104 QD in Part B remained on 8 mg LY3009104 QD in Part C.

Participants who completed Part C received 4 mg LY3009104 QD in Part D.

MTX was administered orally as background therapy.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	Janus Kinase (JAK)1/JAK2, JAK 1/2 Inhibitor, INCB028050
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4 mg LY3009104 once daily for 52 weeks in Part D

Number of subjects in period 4[2]	4 mg LY3009104 QD - Parts C and D	4 to 8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D	8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D
Started	79	47	18
Completed	76	40	17
Not completed	3	7	1
Consent withdrawn by subject	1	2	1
Adverse event, non-fatal	1	2	-
Lost to follow-up	1	3	-

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Participants who completed Part C received 4 mg LY3009104 QD in Part D regardless of dose in Parts B and C.

Baseline characteristics

Reporting groups	
Reporting group title	Part A (Weeks 0 through 12)

Reporting group description: -

Reporting group values	Part A (Weeks 0 through 12)	Total	
Number of subjects	301	301	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	263	263	
From 65-84 years	38	38	
85 years and over	0	0	
Age Continuous Units: years			
arithmetic mean	51.2		
standard deviation	± 11.71	-	
Gender, Male/Female Units: participants			
Female	249	249	
Male	52	52	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	56	56	
Not Hispanic or Latino	227	227	
Unknown or Not Reported	18	18	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	19	19	
Asian	47	47	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	11	11	
White	224	224	
More than one race	0	0	
Unknown or Not Reported	0	0	
Region of Enrollment Units: Subjects			
United States	95	95	
Hungary	13	13	
Czech Republic	23	23	

Mexico	47	47	
Poland	33	33	
Ukraine	29	29	
Croatia	7	7	
Romania	11	11	
India	43	43	
Duration of Rheumatoid Arthritis			
Units: years			
arithmetic mean	5.62		
standard deviation	± 4.401	-	
Tender Joint Counts (TJC)			
TJC 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.			
Units: number of joints			
arithmetic mean	22.2		
standard deviation	± 12.38	-	
Swollen Joint Counts (SJC)			
SJC is the number of swollen joints determined for each participant by examination of 66 joints. Joints were classified as either swollen or not swollen. Swelling was defined as palpable fluctuating synovitis of the joint.			
Units: number of joints			
arithmetic mean	15.8		
standard deviation	± 8.13	-	
High Sensitivity C-Reactive Protein (hsCRP)			
HsCRP is a laboratory analyte that is an indicator of inflammation. Decreases in hsCRP represent reductions in inflammation. Numbers of participants analyzed are 49, 52, 52, 50 for 1 mg, 2 mg, 4 mg, and 8 mg LY3009104 groups respectively, and 97 for placebo group.			
Units: milligrams/liter (mg/L)			
arithmetic mean	12.81		
standard deviation	± 19.402	-	
Erythrocyte Sedimentation Rate (ESR)			
ESR is a laboratory analyte that is an indicator of inflammation. Decreases represent reductions in inflammation.			
Units: millimeters/hour (mm/hr)			
arithmetic mean	38.8		
standard deviation	± 18.39	-	

End points

End points reporting groups

Reporting group title	1 milligram (mg) LY3009104 QD - Part A

Reporting group description:

Administered orally once daily (QD) for 12 weeks in Part A.

Methotrexate (MTX) was administered orally as background therapy.

Reporting group title	2 mg LY3009104 QD - Parts A and B

Reporting group description:

Administered orally QD for 24 weeks in Parts A and B.

MTX was administered orally as background therapy.

Reporting group title	4 mg LY3009104 QD - Parts A and B

Reporting group description:

Administered orally QD for 24 weeks in Parts A and B.

MTX was administered orally as background therapy.

Reporting group title	8 mg LY3009104 QD - Parts A and B

Reporting group description:

Administered orally QD for 24 weeks in Parts A and B.

MTX was administered orally as background therapy.

Reporting group title	Placebo QD - Part A

Reporting group description:

Placebo administered orally QD for 12 weeks in Part A.

MTX was administered orally as background therapy.

Reporting group title	2 mg LY3009104 QD - Parts A and B

Reporting group description:

Administered orally QD for 24 weeks in Parts A and B.

MTX was administered orally as background therapy.

Reporting group title	4 mg LY3009104 QD - Parts A and B

Reporting group description:

Administered orally QD for 24 weeks in Parts A and B.

MTX was administered orally as background therapy.

Reporting group title	8 mg LY3009104 QD - Parts A and B

Reporting group description:

Administered orally QD for 24 weeks in Parts A and B.

MTX was administered orally as background therapy.

Reporting group title	2 mg LY3009104 BID - Part B

Reporting group description:

Participants who received Placebo or 1 mg LY3009104 in Part A were re-randomized at Week 12 to receive 2 mg LY3009104 twice daily (BID) in Part B.

MTX was administered orally as background therapy.

Reporting group title	4 mg LY3009104 QD - Part B

Reporting group description:

Participants who received Placebo or 1 mg LY3009104 in Part A were re-randomized at Week 12 to receive 4 mg LY3009104 QD in Part B.

MTX was administered orally as background therapy.

Reporting group title	4 mg LY3009104 QD - Parts C and D

Reporting group description:

Participants who received 2 mg LY3009104 QD or BID in Part B were re-assigned at Week 24 to 4 mg LY3009104 QD in Part C.

Participants who received 4 mg LY3009104 QD in Part B continued to receive 4 mg LY3009104 QD in Part C.

Participants who completed Part C continued to receive 4 mg LY3009104 QD in Part D.

MTX was administered orally as background therapy.

Reporting group title	4 to 8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D

Reporting group description:

Participants who received 2 mg LY3009104 QD or BID in Part B were re-assigned at Week 24 to 4 mg LY3009104 QD in Part C.

Participants who received 4 mg LY3009104 QD in Part B continued to receive 4 mg LY3009104 QD in Part C.

At Weeks 28 and 32, participants who met dose escalation criteria received 8 mg LY3009104 QD for the rest of Part C.

Dose escalation criteria: ≥ 6 tender and 6 swollen joints based on the 28-joint count assessments and the clinical judgment of the investigator.

Participants who completed Part C received 4 mg LY3009104 QD in Part D.

MTX was administered orally as background therapy.

Reporting group title	8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D

Reporting group description:

Participants who received 8 mg LY3009104 QD in Part B remained on 8 mg LY3009104 QD in Part C.

Participants who completed Part C received 4 mg LY3009104 QD in Part D.

MTX was administered orally as background therapy.

Reporting group title	4 mg LY3009104 QD - Parts C and D

Reporting group description:

Participants who received 2 mg LY3009104 QD or BID in Part B were re-assigned at Week 24 to 4 mg LY3009104 QD in Part C.

Participants who received 4 mg LY3009104 QD in Part B continued to receive 4 mg LY3009104 QD in Part C.

Participants who completed Part C continued to receive 4 mg LY3009104 QD in Part D.

MTX was administered orally as background therapy.

Reporting group title	4 to 8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D

Reporting group description:

Participants who received 2 mg LY3009104 QD or BID in Part B were re-assigned at Week 24 to 4 mg LY3009104 QD in Part C.

Participants who received 4 mg LY3009104 QD in Part B continued to receive 4 mg LY3009104 QD in Part C.

At Weeks 28 and 32, participants who met dose escalation criteria received 8 mg LY3009104 QD for the rest of Part C.

Dose escalation criteria: ≥ 6 tender and 6 swollen joints based on the 28-joint count assessments and the clinical judgment of the investigator.

Participants who completed Part C received 4 mg LY3009104 QD in Part D.

MTX was administered orally as background therapy.

Reporting group title	8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D

Reporting group description:

Participants who received 8 mg LY3009104 QD in Part B remained on 8 mg LY3009104 QD in Part C.

Participants who completed Part C received 4 mg LY3009104 QD in Part D.

MTX was administered orally as background therapy.

Subject analysis set title	Combined 4mg and 8mg ACR20 Response Week 12
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All randomized participants who received placebo, 4 mg or 8 mg LY3009104 in Part A. Participants who had missing components of the ACR20 index at Week 12 had these components imputed by last observation carried forward (LOCF).

Subject analysis set title	4mg ACR20 Response Weeks (Wks) 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D. Participants who had missing components of the ACR20 index at analysis time points had these components imputed by LOCF.

Subject analysis set title	4-8mg ACR20 Response Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D. Participants who had missing components of the ACR20 index at analysis time points had these components imputed by LOCF.

Subject analysis set title	8mg ACR20 Response Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D. Participants who had missing components of the ACR20 index at analysis time points had these components imputed by LOCF.

Subject analysis set title	4mg ACR70 Response Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D. Participants who had missing components of the ACR70 index at analysis time points had these components imputed by LOCF.

Subject analysis set title	4-8mg ACR70 Response Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D. Participants who had missing components of the ACR70 index at analysis time points had these components imputed by LOCF.

Subject analysis set title	8mg ACR70 Response Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D. Participants who had missing components of the ACR70 index at analysis time points had these components imputed by LOCF.

Subject analysis set title	4mg Mean Change TJC and SJC From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had TJC and SJC evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	4-8mg Mean Change TJC and SJC From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had TJC and SJC evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	8mg Mean Change TJC and SJC From Baseline To Wks 76 and 128

Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had TJC and SJC evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	4mg Mean Change HAQ-DI From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had HAQ-DI evaluated at analysis time points. LOCF was used to impute missing post-baseline values

Subject analysis set title	4-8mg Mean Change HAQ-DI From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had HAQ-DI evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	8mg Mean Change HAQ-DI From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had HAQ-DI evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	4mg Mean Change hsCRP From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had hsCRP evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	4-8mg Mean Change hsCRP From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had hsCRP evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	8mg Mean Change hsCRP From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had hsCRP evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	4mg DA Assessment Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had physician's and participant's assessments of disease activity and pain evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	4-8mg DA Assessment Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had physician's and participant's assessments of disease activity and pain evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	8mg DA Assessment Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had physician's and participant's assessments of disease activity and pain evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	2mg LY3009104 PK Assessment for AUC Part A
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All randomized participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data.

Subject analysis set title	4mg LY3009104 PK Assessment for AUC Part A
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All randomized participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data.

Subject analysis set title	8mg LY3009104 PK Assessment for AUC Part A
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All randomized participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data.

Subject analysis set title	4mg Percentage Participants Meeting Low DA Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had DAS28-CRP evaluated at analysis time points.

Subject analysis set title	4-8mg Percentage Participants Meeting Low DA Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had DAS28-CRP evaluated at analysis time points.

Subject analysis set title	8mg Percentage Participants Meeting Low DA Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had DAS28-CRP evaluated at analysis time points.

Subject analysis set title	4mg EULAR28 Response Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had EULAR28 evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	4-8mg EULAR28 Response Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had EULAR28 evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	8mg EULAR28 Response Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had EULAR28 evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	4mg Mean Change ESR From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had ESR evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	4-8mg Mean Change ESR From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had ESR evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	8mg Mean Change ESR From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had ESR evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	2mg LY3009104 PK Assessment for Cmax Part A
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All randomized participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data.

Subject analysis set title	4mg LY3009104 PK Assessment for Cmax Part A
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All randomized participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data.

Subject analysis set title	8mg LY3009104 PK Assessment for Cmax Part A
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All randomized participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data.

Subject analysis set title	4mg Mean Change DAS28-CRP From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had DAS28-CRP evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	4-8mg Mean Change DAS28-CRP From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had DAS28-CRP evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Subject analysis set title	8mg Mean Change DAS28-CRP From Baseline To Wks 76 and 128
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received study drug in Parts C and D and had DAS28-CRP evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

Primary: Percentage of Participants in the 4 mg and 8 mg Dose Groups Who Achieved an American College of Rheumatology 20 (ACR20) Responder Index Response Baseline through Week 12

End point title	Percentage of Participants in the 4 mg and 8 mg Dose Groups Who Achieved an American College of Rheumatology 20 (ACR20) Responder Index Response Baseline through Week 12[1]

End point description:

ACR20 Responder Index is a composite of clinical, laboratory, and functional measures in rheumatoid arthritis (RA). An ACR20 Responder is a participant who had ≥20% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥20% improvement in at least 3 of 5 criteria: Patient's and Physician's Global Assessment of Disease Activity, Health Assessment Questionnaire-Disability Index (HAQ-DI) (assessment of participant’s physical function), pain due to RA, and hsCRP. Participants who discontinue before analysis time point are treated as non-responders. Percentage of participants achieving ACR20 response = (number of ACR20 responders) / (number of participants analyzed) * 100.

End point type	Primary

End point timeframe:

Baseline through Week 12

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All randomized participants who received placebo, 4 mg or 8 mg LY3009104in Part A. Participants for the 4mg and 8mg reporting groups were combined and number of participants analyzed is 102. Participants who had missing components of the ACR20 index at Week 12 had these components imputed by last observation carried forward (LOCF).

End point values	Placebo QD - Part A	Combined 4mg and 8mg ACR20 Response Week 12		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	98	102		
Units: percentage of participants				
number (not applicable)	41	76		

Statistical analyses

Statistical analysis title	Statistical Analysis for Primary Endpoint
Comparison groups	Placebo QD - Part A v Combined 4mg and 8mg ACR20 Response Week 12
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	Regression, Logistic

Notes:

[2] - A priori p-value significance threshold: 1-sided ≤0.10

Secondary: Percentage of Participants Who Achieved an ACR20 Responder Index Response Baseline through Week 12 - Model Based Dose Response

End point title	Percentage of Participants Who Achieved an ACR20 Responder Index Response Baseline through Week 12 - Model Based Dose Response

End point description:

ACR20 Responder Index is a composite of clinical, laboratory, and functional measures in RA. An ACR20 Responder is a participant who had ≥20% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥20% improvement in at least 3 of 5 criteria: Patient's and Physician's Global Assessment of Disease Activity, HAQ-DI (assessment of participant's physical function), pain due to RA, and hsCRP. Participants who discontinue before analysis time point are treated as non-responders. Percentage of participants achieving ACR20 response = (number of ACR20 responders) / (number of participants analyzed) * 100. Data presented are model-based Bayesian posterior mean response rates with 95% credible interval.

End point type	Secondary

End point timeframe:

Baseline through Week 12

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	52	52	50
Units: percentage of participants				
number (confidence interval 95%)	54.6 (42.2 to 67.1)	55.2 (42.3 to 67.6)	74.3 (63.1 to 84.1)	77.2 (65.9 to 86.7)

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	98			
Units: percentage of participants				
number (confidence interval 95%)	42.1 (32.9 to 51.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an ACR20 Responder Index Response Baseline through Week 24

End point title	Percentage of Participants Who Achieved an ACR20 Responder Index Response Baseline through Week 24

End point description:

ACR20 Responder Index is a composite of clinical, laboratory, and functional measures in RA. An ACR20 Responder is a participant who had ≥20% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥20% improvement in at least 3 of 5 criteria: Patient's and Physician's Global Assessment of Disease Activity, HAQ-DI (assessment of participant's physical function), pain due to RA, and hsCRP. Participants who discontinue before analysis time points are treated as non-responders. Percentage of participants achieving ACR20 response = (number of ACR20 responders) / (number of participants treated) * 100.

Participants were not dosed with 1 mg LY3009104 after Week 12; percentage was not calculated. 9999=Data Not Available (N/A).

End point type	Secondary

End point timeframe:

Baseline through Weeks 2, 4, 8, 12, 16, 20, 24

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49[3]	52	52	50
Units: percentage of participants				
number (not applicable)				

Week 2	29	21	42	44
Week 4	43	37	60	54
Week 8	43	42	67	72
Week 12	57	54	75	78
Week 16	9999	63	67	64
Week 20	9999	71	77	78
Week 24	9999	62	75	72

Notes:

[3] - Participants were not dosed with 1 mg LY3009104 after Week 12; percentage was not calculated.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	98[4]			
Units: percentage of participants				
number (not applicable)				
Week 2	11			
Week 4	24			
Week 8	36			
Week 12	41			
Week 16	9999			
Week 20	9999			
Week 24	9999			

Notes:

[4] - Participants were not dosed with placebo after Week 12; percentage was not calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an ACR20 Response Baseline through Weeks 76 and 128

End point title	Percentage of Participants Who Achieved an ACR20 Response Baseline through Weeks 76 and 128

End point description:

ACR20 Responder Index is a composite of clinical, laboratory, and functional measures in RA. An ACR20 Responder is a participant who had ≥20% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥20% improvement in at least 3 of 5 criteria: Patient's and Physician's Global Assessment of Disease Activity, HAQ-DI (assessment of participant’s physical function), pain due to RA, and hsCRP. Participants who discontinue before analysis time points are treated as non-responders. Percentage of participants achieving ACR20 response = (number of ACR20 responders) / (number of participants analyzed) * 100.

End point type	Secondary

End point timeframe:

Baseline through Weeks 76 and 128

End point values	4mg ACR20 Response Weeks (Wks) 76 and 128	4-8mg ACR20 Response Wks 76 and 128	8mg ACR20 Response Wks 76 and 128	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	108	61	32	
Units: percentage of participants				
number (not applicable)				
Week 76 (n=108, 61, 32)	71	67	59	
Week 128 (n=79, 47, 18)	77	57	72	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an ACR 50 Responder Index Response Baseline through Week 24

End point title	Percentage of Participants Who Achieved an ACR 50 Responder Index Response Baseline through Week 24

End point description:

ACR50 Responder Index is a composite of clinical, laboratory, and functional measures in RA. An ACR50 Responder is a participant who had ≥50% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥50% improvement in at least 3 of 5 criteria: Patient's and Physician's Global Assessment of Disease Activity, HAQ-DI (assessment of participant's physical function), pain due to RA, and hsCRP. Participants who discontinue before analysis time points are treated as non-responders. Percentage of participants achieving ACR50 response = (number of ACR50 responders) / (number of participants analyzed) * 100.

Participants were not dosed with 1 mg LY3009104 after Week 12; percentage was not calculated. 9999=Data Not Available (N/A).

End point type	Secondary

End point timeframe:

Baseline through Weeks 2, 4, 8, 12, 16, 20, 24

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49[5]	52	52	50
Units: percentage of participants				
number (not applicable)				
Week 2	0	4	21	4
Week 4	10	10	29	22
Week 8	16	10	33	36
Week 12	31	17	35	40
Week 16	9999	19	38	44
Week 20	9999	27	46	48
Week 24	9999	19	46	54

Notes:

[5] - Participants were not dosed with 1 mg LY3009104 after Week 12; percentage was not calculated.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	98[6]			
Units: percentage of participants				
number (not applicable)				
Week 2	2			
Week 4	3			
Week 8	7			
Week 12	10			
Week 16	9999			
Week 20	9999			
Week 24	9999			

Notes:

[6] - Participants were not dosed with Placebo LY3009104 after Week 12; percentage was not calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an ACR50 Response Baseline through Weeks 76 and 128

End point title	Percentage of Participants Who Achieved an ACR50 Response Baseline through Weeks 76 and 128

End point description:

ACR50 Responder Index is a composite of clinical, laboratory, and functional measures in RA. An ACR50 Responder is a participant who had ≥50% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥50% improvement in at least 3 of 5 criteria: Patient's and Physician's Global Assessment of Disease Activity, HAQ-DI (assessment of participant’s physical function), pain due to RA, and hsCRP. Participants who discontinue before analysis time points are treated as non-responders. Percentage of participants achieving ACR50 response = (number of ACR50 responders) / (number of participants analyzed) * 100.

Participants were not dosed with 1 mg LY3009104 after Week 12; percentage was not calculated. 9999=Data Not Available (N/A).

End point type	Secondary

End point timeframe:

Baseline through Weeks 76 and 128

End point values	4 mg LY3009104 QD - Parts C and D	4 to 8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D	8 mg LY3009104 QD - Part C and 4 mg LY3009104 QD - Part D	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	61	32	
Units: percentage of participants				
number (not applicable)				
Week 76 (n=108, 61, 32)	49	41	44	

Week 128 (n=79, 47, 18)	58	30	44	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an ACR70 Responder Index Response Baseline through Week 24

End point title	Percentage of Participants Who Achieved an ACR70 Responder Index Response Baseline through Week 24

End point description:

ACR70 Responder Index is a composite of clinical, laboratory, and functional measures in RA. An ACR70 Responder is a participant who had ≥70% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥70% improvement in at least 3 of 5 criteria: Patient's and Physician's Global Assessment of Disease Activity, HAQ-DI (assessment of participant's physical function), pain due to RA, and hsCRP. Participants who discontinue before analysis time points are treated as non-responders. Percentage of participants achieving ACR70 response = (number of ACR70 responders) / (number of participants analyzed) * 100.

Participants were not dosed with 1 mg LY3009104 after Week 12; percentage was not calculated. 9999=Data Not Available (N/A).

End point type	Secondary

End point timeframe:

Baseline through Weeks 2, 4, 8, 12, 16, 20, 24

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49[7]	52	52	50
Units: percentage of participants				
number (not applicable)				
Week 2	0	2	12	0
Week 4	2	4	10	6
Week 8	4	4	15	22
Week 12	12	8	23	20
Week 16	9999	8	23	30
Week 20	9999	10	21	26
Week 24	9999	10	27	24

Notes:

[7] - Participants were not dosed with 1 mg LY3009104 after Week 12; percentage was not calculated.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	98[8]			
Units: percentage of participants				

number (not applicable)				
Week 2	0			
Week 4	0			
Week 8	0			
Week 12	2			
Week 16	9999			
Week 20	9999			
Week 24	9999			

Notes:

[8] - Participants were not dosed with placebo after Week 12; percentage was not calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an ACR70 Response Baseline through Weeks 76 and 128

End point title	Percentage of Participants Who Achieved an ACR70 Response Baseline through Weeks 76 and 128

End point description:

ACR70 Responder Index is a composite of clinical, laboratory, and functional measures in RA. An ACR70 Responder is a participant who had ≥70% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥70% improvement in at least 3 of 5 criteria: Patient's and Physician's Global Assessment of Disease Activity, HAQ-DI (assessment of participant's physical function), pain due to RA, and hsCRP. Participants who discontinue before analysis time points are treated as non-responders. Percentage of participants achieving ACR70 response = (number of ACR70 responders) / (number of participants analyzed) * 100.

End point type	Secondary

End point timeframe:

Baseline through Weeks 76 and 128

End point values	4mg ACR70 Response Wks 76 and 128	4-8mg ACR70 Response Wks 76 and 128	8mg ACR70 Response Wks 76 and 128	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	108	61	32	
Units: percentage of participants				
number (not applicable)				
Week 76 (n=108, 61, 32)	29	18	25	
Week 128 (n=79, 47, 18)	28	17	22	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an ACR50 Response Baseline through Week 12 - Model Based Dose Response

End point title	Percentage of Participants Who Achieved an ACR50 Response Baseline through Week 12 - Model Based Dose Response

End point description:

ACR50 Responder Index is a composite of clinical, laboratory, and functional measures in RA. An ACR50 Responder is a participant who had ≥50% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥50% improvement in at least 3 of 5 criteria: Patient's and Physician's Global Assessment of Disease Activity, HAQ-DI (assessment of participant's physical function), pain due to RA, and hsCRP. Participants who discontinue before analysis time point are treated as non-responders. Percentage of participants achieving ACR50 response = (number of ACR50 responders) / (number of participants analyzed) * 100. Data presented are model-based Bayesian posterior mean response rates with 95% credible interval.

End point type	Secondary

End point timeframe:

Baseline through Week 12

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	52	52	50
Units: percentage of participants				
number (confidence interval 95%)	26.5 (16 to 39.2)	18.8 (9.9 to 29.7)	34.4 (23.1 to 46.7)	39.2 (27.1 to 52.2)

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	98			
Units: percentage of participants				
number (confidence interval 95%)	12 (6.5 to 18.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: ACR Percent Improvement (ACR-N)

End point title	ACR 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 a) % of improvement in TJC, b) % of improvement in SJC, and c) third highest percentage of improvement of remaining 5 ACR core criteria: If ≥3 components of the 5 ACR core criteria were missing, then c) was set to missing; if any of 3 components a), b), or c) were missing, then ACR-N was set to missing. Percentage of improvement was truncated to a range of -100 to 100 to minimize impact of outliers (greater scores indicate greater % improvement) and negative scores indicate a decline. Data presented are model-based Bayesian posterior mean response rates with 95% credible interval.

End point type	Secondary

End point timeframe:

Baseline through Week 12

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	52	52	50
Units: percentage of improvement				
number (confidence interval 95%)	17.3 (7.57 to 28.22)	19.42 (8.74 to 29.25)	28.59 (17.67 to 40.83)	29 (17.67 to 41.47)

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	98			
Units: percentage of improvement				
number (confidence interval 95%)	10.97 (-0.39 to 21.64)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Weeks 12 and 24 in Tender and Swollen Joint Counts (TJC and SJC)

End point title	Mean Change from Baseline to Weeks 12 and 24 in Tender and Swollen Joint Counts (TJC and SJC)

End point description:

TJC 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. SJC 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.

Participants were not dosed with 1 mg LY3009104 after Week 12; mean and standard deviation (SD) were not calculated.
9999=Data Not Available (N/A).

All randomized participants who received study drug in Parts A and B and had TJC and SJC evaluated at analysis time points. LOCF was used to impute missing post-baseline values

End point type	Secondary

End point timeframe:

Baseline, Weeks 12 and 24

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49[9]	52	51	50
Units: number of joints				
arithmetic mean (standard deviation)				
TJC - Week 12	-8.4 (± 12.7)	-11.3 (± 13.5)	-12.2 (± 10.45)	-14.7 (± 12.97)
TJC - Week 24	9999 (± 9999)	-12.4 (± 12.6)	-14 (± 9.54)	-17.5 (± 11.23)
SJC - Week 12	-8.1 (± 7.24)	-8.9 (± 9.03)	-9.6 (± 6.49)	-10.4 (± 8.88)
SJC - Week 24	9999 (± 9999)	-10 (± 8.16)	-10.5 (± 6.42)	-12.2 (± 7.29)

Notes:

[9] - Participants were not dosed with 1 mg LY3009104 after Week 12; mean and SD were not calculated.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	98[10]			
Units: number of joints				
arithmetic mean (standard deviation)				
TJC - Week 12	-7.6 (± 12.31)			
TJC - Week 24	9999 (± 9999)			
SJC - Week 12	-6.7 (± 7.97)			
SJC - Week 24	9999 (± 9999)			

Notes:

[10] - Participants were not dosed with placebo after Week 12; mean and SD were not calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Weeks 76 and 128 in TJC and SJC

End point title	Mean Change from Baseline to Weeks 76 and 128 in TJC and SJC

End point description:

TJC 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. SJC 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.

End point type	Secondary

End point timeframe:

Baseline, Weeks 76 and 128

End point values	4mg Mean Change TJC and SJC From Baseline To Wks 76 and 128	4-8mg Mean Change TJC and SJC From Baseline To Wks 76 and 128	8mg Mean Change TJC and SJC From Baseline To Wks 76 and 128	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	108	61	32	
Units: units on a scale				
arithmetic mean (standard deviation)				
TJC - Week 76 (n=108, 61, 32)	-15.7 (± 11.26)	-16 (± 13.37)	-18.1 (± 12.06)	
TJC - Week 128 (n=79, 47, 18)	-16.4 (± 11.01)	-15.3 (± 12.56)	-14 (± 13.68)	
SJC - Week 76 (n=108, 61, 32)	-11.6 (± 6.4)	-12.9 (± 7.8)	-12.4 (± 7.67)	
SJC - Week 128 (n=79, 47, 18)	-11.4 (± 6.81)	-12.4 (± 8.01)	-11.6 (± 6.23)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Weeks 12 and 24 in Health Assessment Questionnaire-Disability Index (HAQ-DI) Score

End point title	Mean Change from Baseline to Weeks 12 and 24 in Health Assessment Questionnaire-Disability Index (HAQ-DI) Score

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 (worst disability). A decrease in HAQ-DI score indicated an improvement in the participant's condition.

Participants were not dosed with 1 mg LY3009104 after Week 12; mean and SD were not calculated. 9999=Data Not Available (N/A).

End point type	Secondary

End point timeframe:

Baseline, Weeks 12 and 24

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49[11]	52	51[12]	50
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 12	-0.35 (± 0.528)	-0.18 (± 0.524)	-0.33 (± 0.459)	-0.39 (± 0.497)
Week 24	9999 (± 9999)	-0.18 (± 0.505)	-0.32 (± 0.506)	-0.44 (± 0.529)

Notes:

[11] - Participants were not dosed with 1 mg LY3009104 after Week 12; mean and SD were not calculated.
[12] - Participants who received study drug in Parts A and B and had evaluable HAQ-DI data.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	98[13]			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 12	-0.1 (± 0.406)			
Week 24	9999 (± 9999)			

Notes:

[13] - Participants were not dosed with placebo after Week 12; mean and SD were not calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Weeks 76 and 128 in HAQ-DI Score

End point title	Mean Change from Baseline to Weeks 76 and 128 in HAQ-DI Score

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 (worst disability). A decrease in HAQ-DI score indicated an improvement in the participant's condition.

End point type	Secondary

End point timeframe:

Baseline, Weeks 76 and 128

End point values	4mg Mean Change HAQ-DI From Baseline To Wks 76 and 128	4-8mg Mean Change HAQ-DI From Baseline To Wks 76 and 128	8mg Mean Change HAQ-DI From Baseline To Wks 76 and 128	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	108	61	32	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 76 (n=108, 61, 32)	-0.34 (± 0.58)	-0.29 (± 0.53)	-0.55 (± 0.58)	
Week 128 (n=79, 47, 18)	-0.31 (± 0.61)	-0.22 (± 0.56)	-0.3 (± 0.66)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Weeks 12 and 24 in High-Sensitivity C-Reactive Protein (hsCRP)

End point title	Mean Change from Baseline to Weeks 12 and 24 in High-Sensitivity C-Reactive Protein (hsCRP)

End point description:

hsCRP is a laboratory analyte that is an indicator of inflammation. Decreases in hsCRP represent reductions in inflammation.

Participants were not dosed with 1 mg LY3009104 after Week 12; mean and SD were not calculated. 9999=Data Not Available (N/A).

End point type	Secondary

End point timeframe:

Baseline, Weeks 12 and 24

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49[14]	52	51[15]	50
Units: mg/L				
arithmetic mean (standard deviation)				
Week 12	-6.14 (± 10.236)	-3.39 (± 19.409)	-7.06 (± 16.945)	-2.32 (± 32.582)
Week 24	9999 (± 9999)	-4.76 (± 19.819)	-4.95 (± 19.819)	-7.61 (± 17.548)

Notes:

[14] - Participants were not dosed with 1 mg LY3009104 after Week 12; mean and SD were not calculated.
[15] - Participants who received study drug in Parts A and B and had evaluable hsCRP data.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	97[16]			
Units: mg/L				
arithmetic mean (standard deviation)				
Week 12	1.5 (± 34.107)			
Week 24	9999 (± 9999)			

Notes:

[16] - Participants were not dosed with placebo after Week 12, therefore mean and SD were not calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Weeks 76 and 128 in hsCRP

End point title	Mean Change from Baseline to Weeks 76 and 128 in hsCRP

End point description:

hsCRP is a laboratory analyte that is an indicator of inflammation. Decreases in hsCRP represent reductions in inflammation.

End point type	Secondary

End point timeframe:

Baseline, Weeks 76 and 128

End point values	4mg Mean Change hsCRP From Baseline To Wks 76 and 128	4-8mg Mean Change hsCRP From Baseline To Wks 76 and 128	8mg Mean Change hsCRP From Baseline To Wks 76 and 128	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	108	61	32	
Units: mg/L				
arithmetic mean (standard deviation)				
Week 76 (n=108, 61, 32)	-3.9 (± 22.43)	-3.3 (± 14.28)	-2.9 (± 25.36)	
Week 128 (n=79, 47, 18)	-6.8 (± 13.66)	-2.9 (± 21.88)	-8.2 (± 12.33)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Weeks 12 and 24 in Erythrocyte Sedimentation Rate (ESR)

End point title	Mean Change from Baseline to Weeks 12 and 24 in Erythrocyte Sedimentation Rate (ESR)

End point description:

ESR is a laboratory analyte that is an indicator of inflammation. Decreases represent reductions in inflammation.

Participants were not dosed with 1 mg LY3009104 after Week 12; mean and SD were not calculated. 9999=Data Not Available (N/A).

End point type	Secondary

End point timeframe:

Baseline, Weeks 12 and 24

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44[17]	51[18]	50[19]	49[20]
Units: mm/hr				
arithmetic mean (standard deviation)				
Week 12 (n=44, 51, 50, 49, 83)	-11.6 (± 14.45)	-6.4 (± 16.81)	-11.5 (± 17.28)	13.9 (± 22.42)

Week 24 (n=0, 50, 48, 45, 0)	9999 (± 9999)	-6.9 (± 13.89)	-9.2 (± 19)	-13.7 (± 21.62)

Notes:

[17] - Participants were not dosed with 1 mg LY3009104 after Week 12; mean and SD were not calculated.

[18] - Participants who received study drug in Parts A and B and had evaluable ESR data.

[19] - Participants who received study drug in Parts A and B and had evaluable ESR data.

[20] - Participants who received study drug in Parts A and B and had evaluable ESR data.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	83[21]			
Units: mm/hr				
arithmetic mean (standard deviation)				
Week 12 (n=44, 51, 50, 49, 83)	-6 (± 19.49)			
Week 24 (n=0, 50, 48, 45, 0)	9999 (± 9999)			

Notes:

[21] - Participants were not dosed with 1 mg LY3009104 after Week 12; mean and SD were not calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Weeks 76 and 128 in ESR

End point title	Mean Change from Baseline to Weeks 76 and 128 in ESR

End point description:

ESR is a laboratory analyte that is an indicator of inflammation. Decreases represent reductions in inflammation.

End point type	Secondary

End point timeframe:

Baseline, Weeks 76 and 128

End point values	4mg Mean Change ESR From Baseline To Wks 76 and 128	4-8mg Mean Change ESR From Baseline To Wks 76 and 128	8mg Mean Change ESR From Baseline To Wks 76 and 128	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	108[22]	61[23]	32[24]	
Units: mm/hr				
arithmetic mean (standard deviation)				
Week 76 (n=108, 61, 32)	-13 (± 18.84)	-7.4 (± 26.28)	-8.9 (± 23.12)	
Week 128 (n=79, 47, 18)	-16 (± 18.74)	-8.5 (± 23.11)	-15.5 (± 23.07)	

Notes:

[22] - Participants who received study drug Parts C and D and had evaluable ESR data.

[23] - Participants who received study drug Parts C and D and had evaluable ESR data.

[24] - Participants who received study drug Parts C and D and had evaluable ESR data.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Weeks 12 and 24 in Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity and Patient's Assessment of Pain

End point title	Mean Change from Baseline to Weeks 12 and 24 in Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity and Patient's Assessment of Pain

End point description:

Physician's and Patient's Assessments of Disease Activity (DA) assessed using a visual analog scale (VAS) that ranged from 0 to 100 millimeters (mm), where 0 indicated no arthritis activity and 100 indicated extremely active arthritis. Patient's assessment of pain due to arthritis was also assessed using a VAS that ranged from 0 (no pain) to 100 mm (worst possible pain).

Participants were not dosed with 1 mg LY3009104 after Week 12; mean and SD were not calculated. 9999=Data Not Available (N/A).

End point type	Secondary

End point timeframe:

Baseline, Weeks 12 and 24

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49[25]	52	51[26]	50
Units: units on a scale				
arithmetic mean (standard deviation)				
Physician's Assessment of DA - Week 12	-23.9 (± 18.49)	-25 (± 20.81)	-30.4 (± 18.75)	-33.5 (± 19.49)
Physician's Assessment of DA - Week 24	9999 (± 9999)	-27.8 (± 21.13)	-35.5 (± 17.72)	-37.8 (± 18.73)
Patient's Assessment of DA - Week 12	-24.9 (± 27.26)	-16.2 (± 22.43)	-25.4 (± 21.61)	-29.8 (± 21.2)
Patient's Assessment of DA - Week 24	9999 (± 9999)	-16.9 (± 24.96)	-30.2 (± 21.85)	-30 (± 20.9)
Patient's Assessment of Pain - Week 12	-22.8 (± 27.39)	-14.2 (± 17.82)	-25 (± 19.22)	-25.3 (± 20.31)
Patient's Assessment of Pain - Week 24	9999 (± 9999)	-14.7 (± 20.57)	-27.3 (± 22.11)	-26.9 (± 19.22)

Notes:

[25] - Participants were not dosed with 1 mg LY3009104 after Week 12; mean and SD were not calculated.
[26] - Participants who received study drug in Parts A and B and had evaluable DA assessment data,

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	98[27]			
Units: units on a scale				
arithmetic mean (standard deviation)				
Physician's Assessment of DA - Week 12	-19 (± 21.4)			
Physician's Assessment of DA - Week 24	9999 (± 9999)			

Patient's Assessment of DA - Week 12	-10.3 (± 22.02)			
Patient's Assessment of DA - Week 24	9999 (± 9999)			
Patient's Assessment of Pain - Week 12	-8.8 (± 22.77)			
Patient's Assessment of Pain - Week 24	9999 (± 9999)			

Notes:

[27] - Participants were not dosed with placebo after Week 12; mean and SD were not calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Weeks 76 and 128 in Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity and Patient's Assessment of Pain

End point title	Mean Change from Baseline to Weeks 76 and 128 in Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity and Patient's Assessment of Pain

End point description:

Physician's and Patient's assessments of DA assessed using a VAS that ranged from 0 to 100 mm, where 0 indicated no arthritis activity and 100 indicated extremely active arthritis. Patient's assessment of pain due to arthritis assessed using a VAS that ranged from 0 (no pain) to 100 mm (worst possible pain).

End point type	Secondary

End point timeframe:

Baseline, Weeks 76 and 128

End point values	4mg DA Assessment Wks 76 and 128	4-8mg DA Assessment Wks 76 and 128	8mg DA Assessment Wks 76 and 128	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	108	61	32	
Units: units on a scale				
arithmetic mean (standard deviation)				
Physician Assessment of DA-Week 76 (n=108, 61, 32)	-40.3 (± 19.15)	-32.3 (± 23.37)	-40.5 (± 21.44)	
Physician Assessment of DA-Week 128 (n=79, 47, 18)	-39.5 (± 20.32)	-31 (± 25.54)	-34 (± 27.51)	
Patient Assessment of DA-Week 76 (n=108, 61, 32)	-27.5 (± 26.49)	-27.5 (± 25.52)	-27.6 (± 24.11)	
Patient Assessment of DA-Week 128 (n=79, 47, 18)	-27.9 (± 27.4)	-19.3 (± 29.72)	-27.6 (± 25.17)	
Patient Assessment of Pain-Week 76 (n=108, 61, 32)	-25.1 (± 24.1)	-27.3 (± 24.24)	-23.4 (± 23.49)	
Patient Assessment of Pain-Week 128 (n=79, 47, 18)	-24.2 (± 24.35)	-18 (± 28.85)	-22.3 (± 22.99)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Weeks 12 and 24 in Disease Activity Score (DAS) Based on the 28 Diarthrodial Joint Count and CRP Level (DAS28-CRP)

End point title	Mean Change from Baseline to Weeks 12 and 24 in Disease Activity Score (DAS) Based on the 28 Diarthrodial Joint Count and CRP 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-28 (TJC28), swollen joint count-28 (SJC28), CRP (mg/L), and Patient's Global Assessment of Disease Activity using VAS (patient's global VAS). DAS28-CRP=0.56*square root (sqrt)(TJC28)+0.28*sqrt(SJC28)+0.36*natural log(CRP+1)+0.014*patient's global VAS+0.96. Scores ranged from 1.0-9.4, where lower scores indicated less disease activity, and remission was DAS28-CRP <2.6. A decrease in DAS28-CRP indicated an improvement in participant's condition.

Participants were not dosed with 1 mg LY3009104 after Week 12; mean and SD were not calculated. 9999=Data Not Available (N/A).

End point type	Secondary

End point timeframe:

Baseline, Weeks 12 and 24

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49[28]	52	50[29]	50
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 12	-1.47 (± 1.299)	-1.4 (± 1.21)	-2.09 (± 1.22)	-2.15 (± 1.273)
Week 24	9999 (± 9999)	-1.53 (± 1.187)	-2.25 (± 1.054)	-2.47 (± 1.28)

Notes:

[28] - Participants were not dosed with 1 mg LY3009104 after Week 12; mean and SD were not calculated.
[29] - Participants who received drug in Parts A and B and had evaluable DAS28-CRP data.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	93[30]			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 12	-0.98 (± 1.141)			
Week 24	9999 (± 9999)			

Notes:

[30] - Participants were not dosed with placebo after Week 12; mean and SD were not calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Weeks 76 and 128 in DAS28-CRP

End point title	Mean Change from Baseline to Weeks 76 and 128 in 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 (mg/L), and Patient's Global Assessment of Disease Activity using visual analog scale (VAS) (patient's global VAS). DAS28-CRP=0.56*square root (sqrt)(TJC28)+0.28*sqrt(SJC28)+0.36*natural log(CRP+1)+0.014*patient's global VAS+0.96. Scores ranged from 1.0-9.4, where lower scores indicated less disease activity and remission is DAS28-CRP <2.6. A decrease in DAS28-CRP indicated an improvement in participant's condition.

End point type	Secondary

End point timeframe:

Baseline, Weeks 76 and 128

End point values	4mg Mean Change DAS28-CRP From Baseline To Wks 76 and 128	4-8mg Mean Change DAS28-CRP From Baseline To Wks 76 and 128	8mg Mean Change DAS28-CRP From Baseline To Wks 76 and 128	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	107[31]	61[32]	31[33]	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 76 (n=107, 61, 31)	-2.47 (± 1.23)	-2.16 (± 1.28)	-2.68 (± 1.12)	
Week 128 (n=79, 47, 18)	-2.56 (± 1.16)	-2.02 (± 1.23)	-2.35 (± 1.4)	

Notes:

[31] - Participants who received study drug in Parts C and D and had evaluable DAS28-CRP data.

[32] - Participants who received study drug in Parts C and D and had evaluable DAS28-CRP data.

[33] - Participants who received study drug in Parts C and D and had evaluable DAS28-CRP data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Responders According to European League Against Rheumatism Responder Index Based on 28-Joint Count (EULAR28) Baseline through Weeks 12 and 24

End point title	Percentage of Responders According to European League Against Rheumatism Responder Index Based on 28-Joint Count (EULAR28) Baseline through Weeks 12 and 24

End point description:

EULAR28 categorizes clinical response based upon improvement since baseline in DAS modified to include the 28-joint count (DAS28) and post-baseline DAS28. DAS28 consists of a composite score of the following variables: TJC28, SJC28, CRP, and Patient's Global Assessment of their Disease Activity (patient's global VAS). DAS28 scores range from 1.0-9.4. EULAR28 categories include: No Response (improvement in DAS28 of ≤0.6 units or post-baseline DAS28 score >5.1 with improvement by ≤1.2 units), Moderate Response (post-baseline DAS28 ≤5.1 with improvement by >0.6 units but ≤1.2 units or post-baseline DAS28 score >3.2 with improvement by >1.2 units), and Good Response (post-baseline DAS28 score ≤3.2 with improvement by >1.2 units).

Participants were not dosed with 1 mg LY3009104 after Week 12; percentage was not calculated. 9999=Data Not Available (N/A).

End point type	Secondary

End point timeframe:

Baseline through Weeks 12 and 24

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49[34]	52	52	50
Units: percentage of participants				
number (not applicable)				
Good Response - Week 12	22	17	46	40
Moderate Response - Week 12	43	63	31	46
No Response - Week 12	35	19	23	14
Good Response - Week 24	9999	25	42	46
Moderate Response - Week 24	9999	52	42	32
No Response - Week 24	9999	23	15	22

Notes:

[34] - Participants were not dosed with 1 mg LY3009104 after Week 12; percentage was not calculated.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	98[35]			
Units: percentage of participants				
number (not applicable)				
Good Response - Week 12	16			
Moderate Response - Week 12	35			
No Response - Week 12	49			
Good Response - Week 24	9999			
Moderate Response - Week 24	9999			
No Response - Week 24	9999			

Notes:

[35] - Participants were not dosed with placebo after Week 12; percentage was not calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Responders According to EULAR28 Baseline through Weeks 76 and 128

End point title	Percentage of Responders According to EULAR28 Baseline through Weeks 76 and 128

End point description:

EULAR28 categorizes clinical response based upon improvement since baseline in Disease Activity Score modified to include the 28-joint count (DAS28) and post-baseline DAS28. DAS28 consists of a composite score of the following variables: tender joint count (TJC28), swollen joint count (SJC28), CRP, and Patient's Global Assessment of their Disease Activity (patient's global VAS). DAS28 scores range from

1.0-9.4. EULAR28 categories include: No Response (improvement in DAS28 of ≤0.6 units or post-baseline DAS28 score >5.1 with improvement by ≤1.2 units), Moderate Response (post-baseline DAS28 ≤5.1 with improvement by >0.6 units but ≤1.2 units or post-baseline DAS28 score >3.2 with improvement by >1.2 units), and Good Response (post-baseline DAS28 score ≤3.2 with improvement by >1.2 units).

All participants who received study drug in Parts C and D and had EULAR28 evaluated at analysis time points. LOCF was used to impute missing post-baseline values.

End point type	Secondary

End point timeframe:

Baseline, Weeks 76 and 128

End point values	4mg EULAR28 Response Wks 76 and 128	4-8mg EULAR28 Response Wks 76 and 128	8mg EULAR28 Response Wks 76 and 128	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	107	61	31	
Units: percentage of participants				
number (not applicable)				
Good Response - Week 76 (n=107, 61, 31)	64	41	55	
Moderate Response - Week 76 (n=107, 61, 31)	27	46	39	
No Response - Week 76 (n=107, 61, 31)	8	13	6	
Good Response - Week 128 (n=79, 47, 18)	65	40	56	
Moderate Response - Week 128 (n=79, 47, 18)	30	40	28	
No Response - Week 128 (n=79, 47, 18)	5	19	17	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Meeting Low Disease Activity and Remission Based on the 28 Diarthrodial Joint Count (DAS28) Baseline through Weeks 12 and 24

End point title	Percentage of Participants Meeting Low Disease Activity and Remission Based on the 28 Diarthrodial Joint Count (DAS28) Baseline through Weeks 12 and 24

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 (mg/L)], and Patient's Global Assessment of Disease Activity using VAS (patient's global VAS). Scores ranged from 1.0-9.4, where lower scores indicated less disease activity. DAS28 scores ≤3.2 are considered as low disease activity, and scores <2.6 are considered as remission. Participants who discontinue before analysis time points are treated as non-responders.

Participants were not dosed with 1 mg LY3009104 after Week 12; percentage was not calculated. 9999=Data Not Available (N/A).

End point type	Secondary

End point timeframe:

Baseline through Weeks 12 and 24

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49[36]	52	52	50
Units: percentage of participants				
number (not applicable)				
Low Disease Activity - Week 12	22	23	48	40
Remission - Week 12	14	15	37	22
Low Disease Activity - Week 24	9999	31	50	46
Remission - Week 24	9999	15	33	36

Notes:

[36] - Participants were not dosed with 1 mg LY3009104 after Week 12; percentage was not calculated.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	98[37]			
Units: percentage of participants				
number (not applicable)				
Low Disease Activity - Week 12	19			
Remission - Week 12	4			
Low Disease Activity - Week 24	9999			
Remission - Week 24	9999			

Notes:

[37] - Participants were not dosed with placebo after Week 12; percentage was not calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Meeting Low Disease Activity and Remission Based on the 28 Diarthrodial Joint Count (DAS28) Baseline through Weeks 76 and 128

End point title	Percentage of Participants Meeting Low Disease Activity and Remission Based on the 28 Diarthrodial Joint Count (DAS28) Baseline through Weeks 76 and 128

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 (mg/L), and Patient's Global Assessment of Disease Activity using VAS (patient's global VAS). Scores ranged from 1.0-9.4, where lower scores indicated less disease activity. DAS28 scores ≤3.2 are considered as low disease activity, and scores <2.6 are considered as remission. Participants who discontinue before analysis time points are treated as non-responders.

End point type	Secondary

End point timeframe:

Baseline through Weeks 76 and 128

End point values	4mg Percentage Participants Meeting Low DA Wks 76 and 128	4-8mg Percentage Participants Meeting Low DA Wks 76 and 128	8mg Percentage Participants Meeting Low DA Wks 76 and 128	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	108	61	32	
Units: percentage of participants				
number (not applicable)				
Low Disease activity - Week 76 (n=108, 61, 32)	58	38	44	
Remission - Week 76 (n=108, 61, 32)	52	21	22	
Low Disease activity - Week 128 (n=79, 47, 18)	59	36	56	
Remission - Week 128 (n=79, 47, 18)	47	26	39	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline through Week 12 in Duration (Minutes) of Morning Stiffness

End point title	Mean Change from Baseline through Week 12 in Duration (Minutes) of Morning Stiffness

End point description:

The Investigator asked participants about the duration of their morning stiffness (in minutes) in and around the joints and recorded the duration. The Investigator asked the participants about duration of morning stiffness on the day prior to the study visit to capture actual symptoms. If morning stiffness duration was longer than 12 hours (720 minutes), it was truncated to 720 minutes for statistical presentations and analyses.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48[38]	51[39]	50[40]	50
Units: minutes				
arithmetic mean (standard deviation)				
Week 4 (n=47, 50, 50, 50, 94)	-34.1 (± 70.49)	-27 (± 46.49)	-57.4 (± 149)	-25.5 (± 126.13)

Week 8 (n=46, 50, 50, 50, 86)	-41.2 (± 85.45)	-31.1 (± 45.8)	-67.8 (± 138.02)	-53.8 (± 101.76)
Week 12 (n=48, 51, 50, 50, 97)	-49.5 (± 72.8)	-30.7 (± 47.41)	-75 (± 142.04)	-62.7 (± 88.27)

Notes:

[38] - Participants who received study drug in Part A and had evaluable morning stiffness data.

[39] - Participants who received study drug in Part A and had evaluable morning stiffness data.

[40] - Participants who received study drug in Part A and had evaluable morning stiffness data.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	97[41]			
Units: minutes				
arithmetic mean (standard deviation)				
Week 4 (n=47, 50, 50, 50, 94)	-22.5 (± 63.61)			
Week 8 (n=46, 50, 50, 50, 86)	-25.5 (± 67.39)			
Week 12 (n=48, 51, 50, 50, 97)	-33.9 (± 97.79)			

Notes:

[41] - Participants who received study drug in Part A and had evaluable morning stiffness data.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Week 12 in Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores

End point title	Mean Change from Baseline to Week 12 in Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores

End point description:

The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains (physical functioning, bodily pain, role limitations due to physical problems and also emotional problems, general health, mental health, social functioning and vitality) and 2 component scores (PCS and MCS). The PCS score consisted of physical functioning, bodily pain, role-physical, and general health scales. The MCS score consisted of social functioning, vitality, mental health, and role-emotional scales. Both PCS and MCS range from 0-100 with higher scores indicating better health or functioning.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48[42]	51[43]	51[44]	50
Units: units on a scale				

arithmetic mean (standard deviation)				
PCS	6.66 (± 8.074)	4.15 (± 7.68)	7.07 (± 7.378)	7 (± 9.054)
MCS	2.54 (± 11.983)	1.89 (± 6.869)	2.39 (± 7.898)	3.03 (± 10.675)

Notes:

[42] - Participants who received study drug in Part A and had evaluable SF-36 data.

[43] - Participants who received study drug in Part A and had evaluable SF-36 data.

[44] - Participants who received study drug in Part A and had evaluable SF-36 data.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	97[45]			
Units: units on a scale				
arithmetic mean (standard deviation)				
PCS	3.22 (± 6.733)			
MCS	0.88 (± 10.437)			

Notes:

[45] - Participants who received study drug in Part A and had evaluable SF-36 data.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Week 12 in Brief Pain Inventory Modified Short Form (BPI-SF Modified) Worst-Pain-in-the-Past-24-hours Item Score

End point title	Mean Change from Baseline to Week 12 in Brief Pain Inventory Modified Short Form (BPI-SF Modified) Worst-Pain-in-the-Past-24-hours Item Score

End point description:

The BPI-sf modified is a self-administered questionnaire developed for the rapid assessment of pain. The BPI-sf modified provides information on the intensity of pain (the sensory dimension) as well as the degree to which pain interferes with function (the reactive dimension). The questionnaire asks questions about pain relief, pain quality, and the participant's perception of the cause of pain. The BPI-sf modified uses a numeric rating scale from 0 (“No pain”) to 10 (“Pain as bad as you can imagine”). Since pain can be quite variable over a day, the BPI-sf modified asked participants to rate their pain at the time of responding to the questionnaire (right now), and also at its worst, least and average over the last 24 hours.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48[46]	51[47]	51[48]	50
Units: units on a scale				
arithmetic mean (standard deviation)	-1.35 (± 2.547)	-0.67 (± 2.132)	-1.41 (± 1.813)	-1.54 (± 2.131)

Notes:

[46] - Participants who received study drug and had evaluable BPI-sf worst-pain-in-the past-24-hours data.
[47] - Participants who received study drug and had evaluable BPI-sf worst-pain-in-the past-24-hours data.
[48] - Participants who received study drug and had evaluable BPI-sf worst-pain-in-the past-24-hours data.

End point values	Placebo QD - Part A			
Subject group type	Reporting group			
Number of subjects analysed	97[49]			
Units: units on a scale				
arithmetic mean (standard deviation)	-0.35 (± 2.136)			

Notes:

[49] - Participants who received study drug and had evaluable BPI-sf worst-pain-in-the past-24-hours data.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline to Week 12 in Functional Assessment of Chronic Illness Therapy-Fatigue Scale (FACIT-F) Score

End point title	Mean Change from Baseline to Week 12 in Functional Assessment of Chronic Illness Therapy-Fatigue Scale (FACIT-F) Score

End point description:

The FACIT-F Scale is a brief 13-item, symptom-specific questionnaire that specifically assesses the participant self-reported severity of fatigue and its impact upon daily activities and functioning. The FACIT-F uses a numeric rating scale of 0 ("Not at all") to 4 ("Very much") for each item to assess fatigue and its impact in the past 7 days. Total scores range from 0 to 52, with higher scores indicating less fatigue.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48[50]	51[51]	51[52]	50
Units: units on a scale				
arithmetic mean (standard deviation)	4.48 (± 10.492)	3.8 (± 9.152)	4.41 (± 8.631)	4.11 (± 9.971)

Notes:

[50] - Participants who received study drug in Part A and had evaluable FACIT-F at Week 12 data.

[51] - Participants who received study drug in Part A and had evaluable FACIT-F at Week 12 data.

[52] - Participants who received study drug in Part A and had evaluable FACIT-F at Week 12 data.

End point values	Placebo QD - Part A			

Subject group type	Reporting group			
Number of subjects analysed	97[53]			
Units: units on a scale				
arithmetic mean (standard deviation)	2.02 (± 8.941)			

Notes:

[53] - Participants who received study drug in Part A and had evaluable FACIT-F at Week 12 data.

Statistical analyses

No statistical analyses for this end point

Secondary: Population Pharmacokinetics (PK): Maximum Concentration at Steady State of Dosing (Cmax,ss) of LY3009104

End point title	Population Pharmacokinetics (PK): Maximum Concentration at Steady State of Dosing (Cmax,ss) of LY3009104[54]

End point description:

End point type	Secondary

End point timeframe:

Baseline through 24 weeks

Notes:

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All randomized participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data. Participants receiving placebo will not have PK data.

End point values	1 milligram (mg) LY3009104 QD - Part A	2mg LY3009104 PK Assessment for Cmax Part A	4mg LY3009104 PK Assessment for Cmax Part A	8mg LY3009104 PK Assessment for Cmax Part A
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	47[55]	91[56]	91[57]	50
Units: nanomoles/Liter (nmol/L)				
geometric mean (geometric coefficient of variation)	36.5 (± 36.1)	59.1 (± 21.3)	119 (± 20.5)	241 (± 22.9)

Notes:

[55] - Participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data.

[56] - Participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data.

[57] - Participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data.

Statistical analyses

No statistical analyses for this end point

Secondary: Population PK: Area Under the Concentration Curve Versus Time at a Dosing Interval at Steady State (AUCtau,ss) of LY3009104

End point title	Population PK: Area Under the Concentration Curve Versus Time at a Dosing Interval at Steady State (AUCtau,ss) of LY3009104[58]

End point description:

End point type	Secondary

End point timeframe:

Baseline through 24 weeks

Notes:

[58] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All randomized participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data. Participants receiving placebo will not have PK data.

End point values	1 milligram (mg) LY3009104 QD - Part A	2mg LY3009104 PK Assessment for AUC Part A	4mg LY3009104 PK Assessment for AUC Part A	8mg LY3009104 PK Assessment for AUC Part A
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	47[59]	91[60]	91[61]	50
Units: nanomoles*hour/Liter (nmol*h/L)				
geometric mean (geometric coefficient of variation)	333 (± 61.7)	541 (± 38)	1060 (± 37)	2190 (± 45.6)

Notes:

[59] - Participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data.

[60] - Participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data.

[61] - Participants who received at least 1 dose of LY3009104 with evaluable LY3009104 PK data.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline through Week 12 in the Ensemble Minimum Data Set 1.0

End point title	Mean Change from Baseline through Week 12 in the Ensemble Minimum Data Set 1.0

End point description:

Zero participants were analyzed. Assessment of Ensemble Minimum Data Set 1.0 was not collected at Week 12 and therefore results are not reported for outcome measure.

End point type	Secondary

End point timeframe:

Baseline, 12 weeks

End point values	1 milligram (mg) LY3009104 QD - Part A	2 mg LY3009104 QD - Parts A and B	4 mg LY3009104 QD - Parts A and B	8 mg LY3009104 QD - Parts A and B
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[62]	0[63]	0[64]	0[65]
Units: number				
number (not applicable)				

Notes:

[62] - Zero participants were analyzed. Assessment of Ensemble Minimum Data Set 1.0 was not collected.
[63] - Zero participants were analyzed. Assessment of Ensemble Minimum Data Set 1.0 was not collected.
[64] - Zero participants were analyzed. Assessment of Ensemble Minimum Data Set 1.0 was not collected.
[65] - Zero participants were analyzed. Assessment of Ensemble Minimum Data Set 1.0 was not collected.

End point values	Placebo QD -			

	Part A			
Subject group type	Reporting group			
Number of subjects analysed	0[66]			
Units: number				
number (not applicable)				

Notes:

[66] - Zero participants were analyzed. Assessment of Ensemble Minimum Data Set 1.0 was not collected.

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:

I4V-MC-JADA

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups

Reporting group title	1 mg LY3009104 once daily Weeks 0-12
Reporting group description: -	
Reporting group title	2 mg LY3009104 once daily Weeks 0-12
Reporting group description: -	
Reporting group title	4 mg LY3009104 once daily Weeks 0-12
Reporting group description: -	
Reporting group title	8 mg LY3009104 once daily Weeks 0-12
Reporting group description: -	
Reporting group title	Placebo once daily Weeks 0-12
Reporting group description: -	
Reporting group title	2 mg LY3009104 twice daily crossover Weeks 12-24
Reporting group description: -	
Reporting group title	4 mg LY3009104 once daily crossover Weeks 12-24
Reporting group description: -	
Reporting group title	2 mg LY3009104 once daily Weeks 12-24
Reporting group description: -	
Reporting group title	4 mg LY3009104 once daily Weeks 12-24
Reporting group description: -	
Reporting group title	8 mg LY3009104 once daily Weeks 12-24
Reporting group description: -	
Reporting group title	4/4 mg LY3009104 once daily Weeks 24-76
Reporting group description: -	
Reporting group title	4:8/4 mg LY3009104 once daily pre-rescue Weeks 24-76
Reporting group description: -	
Reporting group title	4:8/4 mg LY3009104 once daily post-rescue Weeks 24-76
Reporting group description: -	
Reporting group title	8/4 mg LY3009104 once daily Weeks 24-76
Reporting group description: -	
Reporting group title	4/4 mg LY3009104 once daily Weeks 76-128
Reporting group description: -	
Reporting group title	4:8/4 mg LY3009104 once daily Weeks 76-128
Reporting group description: -	
Reporting group title	8/4 mg LY3009104 once daily Weeks 76-128
Reporting group description: -	
Reporting group title	Follow-up

Reporting group description: -

Serious adverse events	1 mg LY3009104 once daily Weeks 0-12	2 mg LY3009104 once daily Weeks 0-12	4 mg LY3009104 once daily Weeks 0-12
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 49 (0.00%)	3 / 52 (5.77%)	2 / 52 (3.85%)
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)			
basal cell carcinoma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[1]	0 / 42 (0.00%)	0 / 44 (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
pregnancy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[2]	0 / 42 (0.00%)	0 / 44 (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 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	0 / 52 (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
pneumothorax			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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			
major depression			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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 creatine phosphokinase increased			
alternative dictionary used:			

MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic enzyme increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transaminases increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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			
fall			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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 16.1			

subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	0 / 52 (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
rib fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scar			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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			
myocardial infarction			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
carotid artery stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
microcytic anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
normochromic normocytic anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancytopenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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			
cataract			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulcerative keratitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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			
coeliac disease			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal obstruction			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal stenosis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diastasis recti abdominis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neck pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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			
acute hepatitis b			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	0 / 52 (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
gastroenteritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
helicobacter gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	1 / 52 (1.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes simplex			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	0 / 52 (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

pneumonia bacterial			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperglycaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
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	8 mg LY3009104 once daily Weeks 0-12	Placebo once daily Weeks 0-12	2 mg LY3009104 twice daily crossover Weeks 12-24
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 50 (2.00%)	3 / 98 (3.06%)	2 / 63 (3.17%)
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)			
basal cell carcinoma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[1]	0 / 41 (0.00%)	0 / 85 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pregnancy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[2]	0 / 41 (0.00%)	0 / 85 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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			
major depression			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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 creatine phosphokinase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic enzyme increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transaminases increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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			

fall			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scar			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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			
myocardial infarction			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
carotid artery stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
microcytic anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	1 / 98 (1.02%)	0 / 63 (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
normochromic normocytic anaemia			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancytopenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 50 (2.00%)	0 / 98 (0.00%)	0 / 63 (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
Eye disorders			
cataract			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulcerative keratitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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			
coeliac disease			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	1 / 98 (1.02%)	0 / 63 (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
colitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal obstruction			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 50 (0.00%)	1 / 98 (1.02%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diastasis recti abdominis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neck pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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 16.1			

subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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			
acute hepatitis b			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
helicobacter gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes simplex			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperglycaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	1 / 98 (1.02%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	4 mg LY3009104 once daily crossover Weeks 12-24	2 mg LY3009104 once daily Weeks 12-24	4 mg LY3009104 once daily Weeks 12-24
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 63 (1.59%)	0 / 51 (0.00%)	0 / 50 (0.00%)

number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 63 (1.59%)	0 / 51 (0.00%)	0 / 50 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[1]	0 / 54 (0.00%)	0 / 43 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pregnancy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[2]	0 / 54 (0.00%)	0 / 43 (0.00%)	0 / 35 (0.00%)
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 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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			
major depression			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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 creatine phosphokinase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic enzyme increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transaminases increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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			
fall			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scar			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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			
myocardial infarction			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
carotid artery stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
microcytic anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
normochromic normocytic anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancytopenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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			
cataract			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulcerative keratitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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			
coeliac disease			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal obstruction			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diastasis recti abdominis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neck pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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			
acute hepatitis b			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
helicobacter gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes simplex			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperglycaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
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	8 mg LY3009104 once daily Weeks 12-24	4/4 mg LY3009104 once daily Weeks 24-76	4:8/4 mg LY3009104 once daily pre-rescue Weeks 24-76
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 49 (6.12%)	16 / 108 (14.81%)	1 / 61 (1.64%)
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)			
basal cell carcinoma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[1]	0 / 40 (0.00%)	0 / 87 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pregnancy			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed[2]	0 / 40 (0.00%)	0 / 87 (0.00%)	0 / 52 (0.00%)
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 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
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 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
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			
major depression			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			

alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	2 / 108 (1.85%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic enzyme increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transaminases increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (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
jaw fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (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
scar			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (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			
myocardial infarction			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
carotid artery stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (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
presyncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
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 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
microcytic anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
normochromic normocytic anaemia			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancytopenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
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			
cataract			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (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
ulcerative keratitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
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			
coeliac disease			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal obstruction			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	0 / 108 (0.00%)	0 / 61 (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
Musculoskeletal and connective tissue disorders			
arthritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (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
diastasis recti abdominis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
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 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neck pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (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 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
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			
acute hepatitis b			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
helicobacter gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes simplex			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	4 / 108 (3.70%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	0 / 108 (0.00%)	0 / 61 (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
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (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
hyperglycaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
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	4:8/4 mg LY3009104 once daily post-rescue Weeks 24-76	8/4 mg LY3009104 once daily Weeks 24-76	4/4 mg LY3009104 once daily Weeks 76-128
Total subjects affected by serious adverse events			

subjects affected / exposed	6 / 61 (9.84%)	6 / 32 (18.75%)	5 / 79 (6.33%)
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)			
basal cell carcinoma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[1]	0 / 52 (0.00%)	0 / 28 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pregnancy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[2]	1 / 52 (1.92%)	0 / 28 (0.00%)	0 / 62 (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
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used:			

MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
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 16.1			
subjects affected / exposed	1 / 61 (1.64%)	0 / 32 (0.00%)	0 / 79 (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
Psychiatric disorders			
major depression			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
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 creatine phosphokinase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic enzyme increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transaminases increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
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			
fall			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	0 / 32 (0.00%)	0 / 79 (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
head injury			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
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 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	1 / 61 (1.64%)	0 / 32 (0.00%)	0 / 79 (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
road traffic accident			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scar			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
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			
myocardial infarction			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	1 / 32 (3.13%)	0 / 79 (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
Nervous system disorders			
carotid artery stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	1 / 32 (3.13%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
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 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
microcytic anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
normochromic normocytic anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	0 / 32 (0.00%)	0 / 79 (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
pancytopenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
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			
cataract			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulcerative keratitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 61 (0.00%)	1 / 32 (3.13%)	0 / 79 (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			
coeliac disease			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	1 / 32 (3.13%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	0 / 32 (0.00%)	0 / 79 (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
large intestinal obstruction			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
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 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diastasis recti abdominis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	0 / 32 (0.00%)	0 / 79 (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
neck pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
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 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
acute hepatitis b			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	1 / 32 (3.13%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
helicobacter gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes simplex			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	1 / 32 (3.13%)	1 / 79 (1.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
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 bacterial			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	1 / 32 (3.13%)	0 / 79 (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
hyperglycaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
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	4:8/4 mg LY3009104 once daily Weeks 76-128	8/4 mg LY3009104 once daily Weeks 76-128	Follow-up
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 47 (6.38%)	0 / 18 (0.00%)	2 / 159 (1.26%)
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)			
basal cell carcinoma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[1]	0 / 40 (0.00%)	0 / 17 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pregnancy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[2]	0 / 40 (0.00%)	0 / 17 (0.00%)	0 / 130 (0.00%)
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 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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			
major depression			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 18 (0.00%)	0 / 159 (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
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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 creatine phosphokinase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hepatic enzyme increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transaminases increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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			
fall			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rib fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scar			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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			
myocardial infarction			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
carotid artery stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 18 (0.00%)	0 / 159 (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
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
microcytic anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
normochromic normocytic anaemia			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancytopenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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			
cataract			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulcerative keratitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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			
coeliac disease			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal obstruction			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestinal stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diastasis recti abdominis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neck pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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 16.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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			
acute hepatitis b			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 18 (0.00%)	0 / 159 (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
gastroenteritis viral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
helicobacter gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes simplex			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
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 16.1			
subjects affected / exposed	2 / 47 (4.26%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia bacterial			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 18 (0.00%)	0 / 159 (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
hyperglycaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Notes:

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

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

Frequency threshold for reporting non-serious adverse events: 4 %

Non-serious adverse events	1 mg LY3009104 once daily Weeks 0-12	2 mg LY3009104 once daily Weeks 0-12	4 mg LY3009104 once daily Weeks 0-12
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 49 (30.61%)	13 / 52 (25.00%)	13 / 52 (25.00%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
blood cholesterol increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	1 / 52 (1.92%)	2 / 52 (3.85%)
occurrences (all)	2	1	2
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	0 / 52 (0.00%)	2 / 52 (3.85%)
occurrences (all)	2	0	2
low density lipoprotein increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
weight increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			

spinal laminectomy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
headache			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	1 / 52 (1.92%)	1 / 52 (1.92%)
occurrences (all)	2	1	1
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
leukopenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
neutropenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
oedema peripheral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences (all)	2	1	0

pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
abdominal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
acquired oesophageal web			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	2	0	0
gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
oesophagitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
sinus congestion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	1 / 52 (1.92%)	2 / 52 (3.85%)
occurrences (all)	1	1	2
nasopharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
pharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	1 / 52 (1.92%)	3 / 52 (5.77%)
occurrences (all)	1	1	3
tooth abscess			

alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	1 / 52 (1.92%)
occurrences (all)	0	1	1
urinary tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	2 / 52 (3.85%)	2 / 52 (3.85%)
occurrences (all)	2	2	2
Metabolism and nutrition disorders			
dyslipidaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	2 / 52 (3.85%)	0 / 52 (0.00%)
occurrences (all)	2	2	0

Non-serious adverse events	8 mg LY3009104 once daily Weeks 0-12	Placebo once daily Weeks 0-12	2 mg LY3009104 twice daily crossover Weeks 12-24
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 50 (30.00%)	18 / 98 (18.37%)	15 / 63 (23.81%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 50 (2.00%)	3 / 98 (3.06%)	0 / 63 (0.00%)
occurrences (all)	3	3	0
blood cholesterol increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 50 (4.00%)	2 / 98 (2.04%)	3 / 63 (4.76%)
occurrences (all)	2	2	3
blood creatine phosphokinase increased			
alternative dictionary used:			

MedDRA 16.1			
subjects affected / exposed	1 / 50 (2.00%)	1 / 98 (1.02%)	1 / 63 (1.59%)
occurrences (all)	1	1	1
low density lipoprotein increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 50 (2.00%)	2 / 98 (2.04%)	4 / 63 (6.35%)
occurrences (all)	1	2	4
weight increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	1 / 98 (1.02%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			
spinal laminectomy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 50 (2.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
headache			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 50 (4.00%)	2 / 98 (2.04%)	2 / 63 (3.17%)
occurrences (all)	3	2	2
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	1 / 98 (1.02%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			

anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
leukopenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 50 (4.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	2	0	0
neutropenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
oedema peripheral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
acquired oesophageal web			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
dyspepsia			

alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	1 / 98 (1.02%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
haemorrhoids			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
oesophagitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	1 / 98 (1.02%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			

back pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 50 (2.00%)	3 / 98 (3.06%)	1 / 63 (1.59%)
occurrences (all)	1	3	1
nasopharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 50 (2.00%)	2 / 98 (2.04%)	1 / 63 (1.59%)
occurrences (all)	1	3	1
pharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
tooth abscess			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 50 (0.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 50 (2.00%)	2 / 98 (2.04%)	2 / 63 (3.17%)
occurrences (all)	1	2	2
urinary tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 50 (4.00%)	4 / 98 (4.08%)	1 / 63 (1.59%)
occurrences (all)	2	4	1
Metabolism and nutrition disorders			
dyslipidaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 50 (2.00%)	0 / 98 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
hypercholesterolaemia			

alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 50 (4.00%)	2 / 98 (2.04%)	1 / 63 (1.59%)
occurrences (all)	2	2	1

Non-serious adverse events	4 mg LY3009104 once daily crossover Weeks 12-24	2 mg LY3009104 once daily Weeks 12-24	4 mg LY3009104 once daily Weeks 12-24
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 63 (15.87%)	12 / 51 (23.53%)	10 / 50 (20.00%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	1 / 51 (1.96%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
blood cholesterol increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 63 (1.59%)	0 / 51 (0.00%)	1 / 50 (2.00%)
occurrences (all)	1	0	1
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	2 / 51 (3.92%)	1 / 50 (2.00%)
occurrences (all)	0	2	1
low density lipoprotein increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 63 (1.59%)	1 / 51 (1.96%)	1 / 50 (2.00%)
occurrences (all)	1	1	1
weight increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	1 / 51 (1.96%)	4 / 50 (8.00%)
occurrences (all)	0	1	5
Surgical and medical procedures			

spinal laminectomy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 63 (1.59%)	1 / 51 (1.96%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
leukopenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
neutropenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
oedema peripheral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1

pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	1 / 51 (1.96%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
acquired oesophageal web			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 63 (1.59%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	1 / 51 (1.96%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
haemorrhoids			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
oesophagitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 63 (1.59%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 63 (1.59%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 63 (3.17%)	2 / 51 (3.92%)	0 / 50 (0.00%)
occurrences (all)	2	2	0
nasopharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	2 / 51 (3.92%)	0 / 50 (0.00%)
occurrences (all)	0	2	0
tooth abscess			

alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	4 / 63 (6.35%)	2 / 51 (3.92%)	1 / 50 (2.00%)
occurrences (all)	4	2	1
urinary tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 63 (1.59%)	2 / 51 (3.92%)	1 / 50 (2.00%)
occurrences (all)	1	2	1
Metabolism and nutrition disorders			
dyslipidaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 63 (0.00%)	0 / 51 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	8 mg LY3009104 once daily Weeks 12-24	4/4 mg LY3009104 once daily Weeks 24-76	4:8/4 mg LY3009104 once daily pre-rescue Weeks 24-76
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 49 (36.73%)	35 / 108 (32.41%)	7 / 61 (11.48%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	1 / 108 (0.93%)	0 / 61 (0.00%)
occurrences (all)	1	1	0
blood cholesterol increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	3 / 49 (6.12%)	3 / 108 (2.78%)	0 / 61 (0.00%)
occurrences (all)	4	4	0
blood creatine phosphokinase increased			

alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	1 / 108 (0.93%)	1 / 61 (1.64%)
occurrences (all)	2	1	1
low density lipoprotein increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	3 / 49 (6.12%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	3	0	0
weight increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	1 / 108 (0.93%)	0 / 61 (0.00%)
occurrences (all)	1	1	0
Surgical and medical procedures			
spinal laminectomy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
headache			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	1 / 61 (1.64%)
occurrences (all)	0	1	1
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	0 / 108 (0.00%)	1 / 61 (1.64%)
occurrences (all)	1	0	1
leukopenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
neutropenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
oedema peripheral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
acquired oesophageal web			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
dyspepsia			

alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 49 (2.04%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
haemorrhoids			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
oesophagitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0
sinus congestion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			

back pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	9 / 108 (8.33%)	0 / 61 (0.00%)
occurrences (all)	0	9	0
nasopharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	2 / 108 (1.85%)	0 / 61 (0.00%)
occurrences (all)	2	2	0
pharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	1 / 108 (0.93%)	1 / 61 (1.64%)
occurrences (all)	0	1	1
tooth abscess			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	9 / 108 (8.33%)	1 / 61 (1.64%)
occurrences (all)	2	10	1
urinary tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 49 (4.08%)	12 / 108 (11.11%)	1 / 61 (1.64%)
occurrences (all)	2	15	1
Metabolism and nutrition disorders			
dyslipidaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 49 (0.00%)	0 / 108 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			

alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	4 / 49 (8.16%)	1 / 108 (0.93%)	1 / 61 (1.64%)
occurrences (all)	4	1	1

Non-serious adverse events	4:8/4 mg LY3009104 once daily post-rescue Weeks 24-76	8/4 mg LY3009104 once daily Weeks 24-76	4/4 mg LY3009104 once daily Weeks 76-128
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 61 (40.98%)	16 / 32 (50.00%)	24 / 79 (30.38%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences (all)	0	0	1
blood cholesterol increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	4 / 79 (5.06%)
occurrences (all)	0	0	4
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 61 (3.28%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences (all)	2	0	1
low density lipoprotein increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	3 / 79 (3.80%)
occurrences (all)	0	0	3
weight increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	3 / 61 (4.92%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences (all)	3	0	1
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			

spinal laminectomy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	2 / 32 (6.25%)	0 / 79 (0.00%)
occurrences (all)	0	2	0
headache			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	2 / 32 (6.25%)	1 / 79 (1.27%)
occurrences (all)	0	2	1
leukopenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	0	0	0
neutropenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	1 / 32 (3.13%)	1 / 79 (1.27%)
occurrences (all)	0	1	1
General disorders and administration site conditions			
oedema peripheral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	1 / 32 (3.13%)	0 / 79 (0.00%)
occurrences (all)	2	1	0

pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	1 / 32 (3.13%)	0 / 79 (0.00%)
occurrences (all)	0	1	0
acquired oesophageal web			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	1	0	0
gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	2 / 32 (6.25%)	0 / 79 (0.00%)
occurrences (all)	0	2	0
oesophagitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	1 / 32 (3.13%)	0 / 79 (0.00%)
occurrences (all)	0	1	0
sinus congestion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences (all)	1	0	1
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 61 (0.00%)	2 / 32 (6.25%)	1 / 79 (1.27%)
occurrences (all)	0	2	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	3 / 61 (4.92%)	5 / 32 (15.63%)	3 / 79 (3.80%)
occurrences (all)	3	5	3
nasopharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	4 / 61 (6.56%)	1 / 32 (3.13%)	7 / 79 (8.86%)
occurrences (all)	4	1	9
pharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	2 / 32 (6.25%)	2 / 79 (2.53%)
occurrences (all)	1	3	2
tooth abscess			

alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	0 / 32 (0.00%)	0 / 79 (0.00%)
occurrences (all)	1	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	6 / 61 (9.84%)	1 / 32 (3.13%)	3 / 79 (3.80%)
occurrences (all)	8	1	5
urinary tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	5 / 61 (8.20%)	3 / 32 (9.38%)	3 / 79 (3.80%)
occurrences (all)	6	3	4
Metabolism and nutrition disorders			
dyslipidaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 61 (3.28%)	2 / 32 (6.25%)	4 / 79 (5.06%)
occurrences (all)	2	2	4
hypercholesterolaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 61 (1.64%)	0 / 32 (0.00%)	1 / 79 (1.27%)
occurrences (all)	1	0	1

Non-serious adverse events	4:8/4 mg LY3009104 once daily Weeks 76-128	8/4 mg LY3009104 once daily Weeks 76-128	Follow-up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 47 (27.66%)	10 / 18 (55.56%)	5 / 159 (3.14%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	3 / 47 (6.38%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	4	0	0
blood cholesterol increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used:			

MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
low density lipoprotein increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
spinal laminectomy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	1	1	0
headache			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			

anaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
leukopenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	0	2	0
neutropenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
oedema peripheral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 18 (0.00%)	1 / 159 (0.63%)
occurrences (all)	1	0	1
pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
abdominal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	1	1	0
acquired oesophageal web			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
dyspepsia			

alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
haemorrhoids			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	1	1	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
oesophagitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
oropharyngeal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
sinus congestion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 18 (5.56%)	1 / 159 (0.63%)
occurrences (all)	0	1	1
Musculoskeletal and connective tissue disorders			

back pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 47 (4.26%)	1 / 18 (5.56%)	1 / 159 (0.63%)
occurrences (all)	2	1	1
nasopharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 47 (4.26%)	2 / 18 (11.11%)	0 / 159 (0.00%)
occurrences (all)	2	3	0
pharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
tooth abscess			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	1	1	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 47 (4.26%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	3	1	0
urinary tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 47 (2.13%)	0 / 18 (0.00%)	2 / 159 (1.26%)
occurrences (all)	1	0	2
Metabolism and nutrition disorders			
dyslipidaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	0 / 18 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			

alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 47 (0.00%)	1 / 18 (5.56%)	0 / 159 (0.00%)
occurrences (all)	0	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 May 2011	Amendment I4V-MC-JADA(a): An open-label extension period (referred to as Part C of the study) was added as an optional extension of the study for patients who completed 24 weeks of treatment and met enrollment criteria. The open-label extension period was added to collect additional safety data, and to examine the effect of long-term administration of LY3009104 on efficacy measures. o New secondary and exploratory objectives were added to evaluate the safety and tolerability of long-term administration of LY3009104, and to examine the effects of long-term administration of LY3009104 on patient-reported outcomes. o Blinding information was clarified throughout the document to distinguish the double-blind period (Part A and Part B) and the open-label extension period (Part C). o Additional inclusion and exclusion criteria applicable to Part C of the study were added. Inclusion and exclusion criteria for Parts A and B were revised. o Study design for Part C was provided. Study design for Parts A and B was updated. o Use of concomitant medications during Part C of the study was added. o The study schedule (Attachment 1 of the protocol amendment) of Parts A and B was updated. A study schedule was added to include assessments of Part C of the study. o Treatment assignment for Part C of the study and dose escalation process during the open-label extension period were added.
29 June 2012	Amendment I4V-MC-JADA(b) - An additional open-label extension period (referred to as Part D of the study) was added as an optional extension of the study for patients who completed 76 weeks of treatment and met enrollment criteria. This additional extension would allow for further evaluation of longer-term administration in patients who may have been receiving therapeutic benefit of 4 mg LY3009104 once daily and assist in characterization of the safety and tolerability profile of LY3009104. All patients who entered Part D would receive 4 mg LY3009104 once daily. o Secondary and exploratory objectives were updated to reflect the addition of Part D. o Blinding information was updated to reflect the addition of Part D. o Additional inclusion and exclusion criteria applicable to Part D of the study were added. o Study design for Part D was provided. o Use of concomitant medications was updated to reflect the addition of Part D of the study. o A study schedule was added to include assessments of Part D of the study. o Treatment assignment for Part D of the study was added. • Statistical methods were revised to reflect the addition of Part D. • In general, changes were made to clarify study procedures and to keep consistency throughout the protocol. • Editorial revisions with no impact on protocol design or implementation also were made.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported