



Clinical trial results:

An Adaptive Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of LY3471851 (NKTR-358) in Patients with Moderately to Severely Active Ulcerative Colitis

Summary

EudraCT number	2020-003017-35
Trial protocol	FR SK HU CZ BE PL LV
Global end of trial date	09 August 2022

Results information

Result version number	v1 (current)
This version publication date	12 November 2023
First version publication date	12 November 2023

Trial information

Trial identification

Sponsor protocol code	J1P-MC-KFAH
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04677179
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 17287

Notes:

Sponsors

Sponsor organisation name	Nektar Therapeutics
Sponsor organisation address	455 Mission Bay Blvd. South, San Francisco, United States, 94158
Public contact	Nektar Therapeutics, Clinical Trial Information Desk, Nektar Therapeutics, 1 855-482-8676, studyinquiry@nektar.com
Scientific contact	Nektar Therapeutics, Clinical Trial Information Desk, Nektar Therapeutics, 1 855-482-8676, studyinquiry@nektar.com

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	09 August 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	09 August 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The reason for this study is to determine if the study drug LY3471851 is safe and effective in adult participants with active ulcerative colitis (UC). The study treatment will last about 52 weeks.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 March 2021
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	Argentina: 4
Country: Number of subjects enrolled	Australia: 1
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Czechia: 6
Country: Number of subjects enrolled	Hungary: 6
Country: Number of subjects enrolled	Japan: 5
Country: Number of subjects enrolled	Korea, Republic of: 5
Country: Number of subjects enrolled	Latvia: 5
Country: Number of subjects enrolled	Poland: 5
Country: Number of subjects enrolled	Russian Federation: 13
Country: Number of subjects enrolled	Slovakia: 3
Country: Number of subjects enrolled	Ukraine: 18
Country: Number of subjects enrolled	United States: 8
Country: Number of subjects enrolled	China: 1
Worldwide total number of subjects	81
EEA total number of subjects	26

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	77
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study consisted of:

-a 12-week induction treatment period: participants randomly received either high dose LY3471851 or low dose LY3471851 or placebo.

-a 40-week maintenance/extension treatment period (final dose at week 50 and study assessments at week 52) (Continued..)

Pre-assignment

Screening details:

a 6-week post-treatment follow-up period: Following treatment completion or discontinuation, participants entered the follow-up period and were observed for safety. No treatments were administered.

Period 1

Period 1 title	Induction Treatment Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	High dose LY3471851 (Induction Treatment Period)

Arm description:

Participants received a subcutaneous injection of high dose LY3471851 every 2 weeks from weeks 0 to 12.

Arm type	Experimental
Investigational medicinal product name	LY3471851
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a subcutaneous injection of high dose LY3471851 every 2 weeks from weeks 0 to 12.

Arm title	Low dose LY3471851 (Induction Treatment Period)
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Arm description:

Participants received a subcutaneous injection of low dose LY3471851 every 2 weeks from weeks 0 to 12.

Arm type	Experimental
Investigational medicinal product name	LY3471851
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a subcutaneous injection of low dose LY3471851 every 2 weeks from weeks 0 to 12.

Arm title	Placebo (Induction Treatment Period)
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Arm description:

Participants received a subcutaneous injection of placebo every 2 weeks from weeks 0 to 12.

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

Dosage and administration details:

Participants received a subcutaneous injection of placebo every 2 weeks from weeks 0 to 12.

Number of subjects in period 1	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Induction Treatment Period)
Started	32	35	14
Received at Least One Dose of Study Drug	32	35	14
Completed	19	22	12
Not completed	13	13	2
Physician decision	1	-	1
Consent withdrawn by subject	4	1	1
Adverse event, non-fatal	1	-	-
Study terminated by sponsor	7	11	-
Protocol deviation	-	1	-

Period 2

Period 2 title	Maintenance/Extension Treatment Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	No
Arm title	High Dose LY3471851 (Maintenance Treatment Period)

Arm description:

Week 12 responders from the high dose LY3471851 induction treatment period arm entered the maintenance period and continued with the same treatment.

Arm type	Experimental
Investigational medicinal product name	LY3471851
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a subcutaneous injection of high dose LY3471851 every 2 weeks with final dose at

Arm title	Low dose LY3471851 (Maintenance Treatment Period)
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Arm description:

Week 12 responders from the low dose LY3471851 induction treatment period arm entered the maintenance period and continued with the same treatment.

Arm type	Experimental
Investigational medicinal product name	LY3471851
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a subcutaneous injection of low dose LY3471851 every 2 weeks with final dose at week 50.

Arm title	Placebo (Maintenance Treatment Period)
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Arm description:

Week 12 responders from the placebo induction treatment period arm entered the maintenance period and continued with the same treatment.

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

Dosage and administration details:

Participants received a subcutaneous injection of placebo every 2 weeks with final dose at week 50.

Arm title	High dose LY3471851 (Extension Treatment Period)
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Arm description:

Week 12 non-responders entered the extension period where they received subcutaneous injection of high dose LY3471851 every 2 weeks up to week 50. At week 26, extension period non-responders were discontinued from treatment.

Arm type	Experimental
Investigational medicinal product name	LY3471851
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a subcutaneous injection of high dose LY3471851 every 2 weeks with final dose at week 50. At week 26, non-responders were discontinued from treatment.

Number of subjects in period 2	High Dose LY3471851 (Maintenance Treatment Period)	Low dose LY3471851 (Maintenance Treatment Period)	Placebo (Maintenance Treatment Period)
Started	8	10	5
Completed	0	0	0
Not completed	8	10	5
Consent withdrawn by subject	1	-	-
Study terminated by sponsor	7	9	5
Lack of efficacy	-	1	-

Number of subjects in period 2	High dose LY3471851 (Extension Treatment Period)
Started	26
Completed	0
Not completed	26
Consent withdrawn by subject	2
Study terminated by sponsor	18
Lack of efficacy	6

Period 3

Period 3 title	Post-Treatment Follow-up Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	No
Arm title	High dose LY3471851 (Post-Treatment Follow-up Period)

Arm description:

Participants randomised to high dose LY3471851 arm entered follow-up period from induction or maintenance, or extension periods and were observed for 6 weeks for safety. No treatments were administered.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Arm title	Low dose LY3471851 (Post-Treatment Follow-up Period)
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Arm description:

Participants randomised to low dose LY3471851 arm entered follow-up period from induction or maintenance, or extension periods and were observed for 6 weeks for safety. No treatments were administered.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Arm title	Placebo (Post-Treatment Follow-up Period)
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Arm description:

Participants randomised to placebo arm entered follow-up period from induction or maintenance, or extension periods and were observed for 6 weeks for safety. No treatments were administered.

Arm type	No intervention
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No investigational medicinal product assigned in this arm

Number of subjects in period 3	High dose LY3471851 (Post-Treatment Follow-up Period)	Low dose LY3471851 (Post-Treatment Follow-up Period)	Placebo (Post-Treatment Follow-up Period)
Started	25	30	11
Completed	0	0	0
Not completed	25	30	11
Consent withdrawn by subject	3	1	-
Adverse event, non-fatal	1	-	-
Study terminated by sponsor	18	26	11
Lost to follow-up	1	-	-
Lack of efficacy	2	3	-

Baseline characteristics

Reporting groups

Reporting group title	High dose LY3471851 (Induction Treatment Period)
Reporting group description:	
Participants received a subcutaneous injection of high dose LY3471851 every 2 weeks from weeks 0 to 12.	
Reporting group title	Low dose LY3471851 (Induction Treatment Period)
Reporting group description:	
Participants received a subcutaneous injection of low dose LY3471851 every 2 weeks from weeks 0 to 12.	
Reporting group title	Placebo (Induction Treatment Period)
Reporting group description:	
Participants received a subcutaneous injection of placebo every 2 weeks from weeks 0 to 12.	

Reporting group values	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Induction Treatment Period)
Number of subjects	32	35	14
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	39.2	44.5	45.7
standard deviation	± 12.5	± 13.8	± 15.2
Gender categorical Units: Subjects			
Female	10	9	6
Male	22	26	8
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	5	4	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	0	0
White	25	31	12
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment			

Units: Subjects			
Argentina	2	1	1
Australia	0	1	0
Belgium	0	0	1
Czechia	2	4	0
Hungary	3	3	0
Japan	3	1	1
South Korea	1	3	1
Latvia	2	3	0
Poland	2	2	1
Russia	5	5	3
Slovakia	1	1	1
Ukraine	7	7	4
United States	3	4	1
China	1	0	0

Reporting group values	Total		
Number of subjects	81		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	25		
Male	56		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0		
Asian	11		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	2		
White	68		
More than one race	0		
Unknown or Not Reported	0		
Region of Enrollment			
Units: Subjects			
Argentina	4		

Australia	1		
Belgium	1		
Czechia	6		
Hungary	6		
Japan	5		
South Korea	5		
Latvia	5		
Poland	5		
Russia	13		
Slovakia	3		
Ukraine	18		
United States	8		
China	1		

End points

End points reporting groups

Reporting group title	High dose LY3471851 (Induction Treatment Period)
Reporting group description: Participants received a subcutaneous injection of high dose LY3471851 every 2 weeks from weeks 0 to 12.	
Reporting group title	Low dose LY3471851 (Induction Treatment Period)
Reporting group description: Participants received a subcutaneous injection of low dose LY3471851 every 2 weeks from weeks 0 to 12.	
Reporting group title	Placebo (Induction Treatment Period)
Reporting group description: Participants received a subcutaneous injection of placebo every 2 weeks from weeks 0 to 12.	
Reporting group title	High Dose LY3471851 (Maintenance Treatment Period)
Reporting group description: Week 12 responders from the high dose LY3471851 induction treatment period arm entered the maintenance period and continued with the same treatment.	
Reporting group title	Low dose LY3471851 (Maintenance Treatment Period)
Reporting group description: Week 12 responders from the low dose LY3471851 induction treatment period arm entered the maintenance period and continued with the same treatment.	
Reporting group title	Placebo (Maintenance Treatment Period)
Reporting group description: Week 12 responders from the placebo induction treatment period arm entered the maintenance period and continued with the same treatment.	
Reporting group title	High dose LY3471851 (Extension Treatment Period)
Reporting group description: Week 12 non-responders entered the extension period where they received subcutaneous injection of high dose LY3471851 every 2 weeks up to week 50. At week 26, extension period non-responders were discontinued from treatment.	
Reporting group title	High dose LY3471851 (Post-Treatment Follow-up Period)
Reporting group description: Participants randomised to high dose LY3471851 arm entered follow-up period from induction or maintenance, or extension periods and were observed for 6 weeks for safety. No treatments were administered.	
Reporting group title	Low dose LY3471851 (Post-Treatment Follow-up Period)
Reporting group description: Participants randomised to low dose LY3471851 arm entered follow-up period from induction or maintenance, or extension periods and were observed for 6 weeks for safety. No treatments were administered.	
Reporting group title	Placebo (Post-Treatment Follow-up Period)
Reporting group description: Participants randomised to placebo arm entered follow-up period from induction or maintenance, or extension periods and were observed for 6 weeks for safety. No treatments were administered.	

Primary: Percentage of Participants Who Achieved Clinical Remission at Week 12

End point title	Percentage of Participants Who Achieved Clinical Remission at Week 12
End point description: Clinical remission is defined as achieving a Modified Mayo Score (MMS) sub-score for rectal bleeding=0, stool frequency=0, or stool frequency=1 with ≥ 1 point decrease from baseline, and endoscopy=0 or 1 (excluding friability). The MMS is a scoring system for assessment of UC and is composed of sub-scores	

of stool frequency (range: 0 to 3, where 0=normal number of stools, 3=5 or more stools more than normal), endoscopy (range: 0 to 3, where 0=normal or inactive disease, 3=severe disease [spontaneous bleeding, ulceration]), rectal bleeding (range: 0 to 3, where 0=no blood seen, 3=blood alone passed). Total MMS score is sum of all sub-scores and ranges from 0 to 9, with higher scores indicating higher disease activity.

End point type	Primary
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End point timeframe:

Week 12

Analysis Population Description (APD): All randomized participants who received at least one dose of study drug and had MMS data at week 12.

End point values	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Induction Treatment Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	28	14	
Units: percentage of participants				
number (confidence interval 95%)	17.2 (3.5 to 31)	7.1 (0 to 16.7)	14.3 (0 to 32.6)	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (Induction Treatment Period) v Low dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.75
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.03
upper limit	11.32

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (Induction Treatment Period) v High dose LY3471851 (Induction Treatment Period)

Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.838
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	6.21

Secondary: Percentage of Participants Who Achieved Clinical Response at Week 12

End point title	Percentage of Participants Who Achieved Clinical Response at Week 12
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End point description:

Clinical response is defined as a decrease in the MMS of ≥ 2 points and $\geq 30\%$ decrease from baseline, and a decrease of ≥ 1 point in the rectal bleeding sub-score from baseline or a rectal bleeding score of 0 or 1. The MMS is a scoring system for assessment of UC and is composed of sub-scores of stool frequency (range: 0 to 3, where 0=normal number of stools, 3=5 or more stools more than normal), endoscopy (range: 0 to 3, where 0=normal or inactive disease, 3=severe disease [spontaneous bleeding, ulceration]), rectal bleeding (range: 0 to 3, where 0=no blood seen, 3=blood alone passed). Total MMS score is sum of all sub-scores and ranges from 0 to 9, with higher scores indicating higher disease activity.

End point type	Secondary
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End point timeframe:

Week 12

APD: All randomized participants who received at least one dose of study drug and had MMS data at week 12.

End point values	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Induction Treatment Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	28	14	
Units: percentage of participants				
number (confidence interval 95%)	41.4 (23.5 to 59.3)	39.3 (21.2 to 57.4)	35.7 (10.6 to 60.8)	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (Induction Treatment Period) v Low dose LY3471851 (Induction Treatment Period)

Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.563
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	3.3

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (Induction Treatment Period) v High dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.759
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	3.64

Secondary: Percentage of Participants Who Achieved Endoscopic Remission at Week 12

End point title	Percentage of Participants Who Achieved Endoscopic Remission at Week 12
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End point description:

Endoscopic remission is defined as achieving a MMS sub-score for endoscopy=0 or 1 (excluding friability). The MMS is a scoring system for assessment of UC and is composed of sub-scores of stool frequency (range: 0 to 3, where 0=normal number of stools, 3=5 or more stools more than normal), endoscopy (range: 0 to 3, where 0=normal or inactive disease, 3=severe disease [spontaneous bleeding, ulceration]), rectal bleeding (range: 0 to 3, where 0=no blood seen, 3=blood alone passed). Total MMS score is sum of all sub-scores and ranges from 0 to 9, with higher scores indicating higher disease activity.

End point type	Secondary
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End point timeframe:

Week 12

APD: All randomized participants who received at least one dose of study drug and had MMS data at week 12.

End point values	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Induction Treatment Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	28	14	
Units: percentage of participants				
number (confidence interval 95%)	24.1 (8.6 to 39.7)	14.3 (1.3 to 27.2)	28.6 (4.9 to 52.2)	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (Induction Treatment Period) v Low dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.163
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.02
upper limit	1.93

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (Induction Treatment Period) v High dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.439
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.11
upper limit	2.77

Secondary: Percentage of Participants Who Achieved Endoscopic Response at Week 12

End point title	Percentage of Participants Who Achieved Endoscopic Response at Week 12
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End point description:

Endoscopic response is defined as a decrease of ≥ 1 point in the MMS endoscopy sub-score from baseline. The MMS is a scoring system for assessment of UC and is composed of sub-scores of stool frequency (range: 0 to 3, where 0=normal number of stools, 3=5 or more stools more than normal), endoscopy (range: 0 to 3, where 0=normal or inactive disease, 3=severe disease [spontaneous bleeding, ulceration]), rectal bleeding (range: 0 to 3, where 0=no blood seen, 3=blood alone passed). Total MMS score is sum of all sub-scores and ranges from 0 to 9, with higher scores indicating higher disease activity.

End point type	Secondary
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End point timeframe:

Week 12

APD: All randomized participants who received at least one dose of study drug and had MMS data at week 12.

End point values	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Induction Treatment Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	28	14	
Units: percentage of participants				
number (confidence interval 95%)	37.9 (20.3 to 55.6)	32.1 (14.8 to 49.4)	21.4 (0 to 42.9)	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (Induction Treatment Period) v Low dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.821
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	9.88

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (Induction Treatment Period) v High dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.572
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	5.49

Secondary: Percentage of Participants Who Achieved Symptomatic Remission at week 12

End point title	Percentage of Participants Who Achieved Symptomatic Remission at week 12
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End point description:

Symptomatic remission is defined as achieving a MMS sub-score for stool frequency=0, or stool frequency=1 with a decrease of ≥ 1 point from baseline, and rectal bleeding =0. The MMS is a scoring system for assessment of UC and is composed of sub-scores of stool frequency (range: 0 to 3, where 0=normal number of stools, 3=5 or more stools more than normal), endoscopy (range: 0 to 3, where 0=normal or inactive disease, 3=severe disease [spontaneous bleeding, ulceration]), rectal bleeding (range: 0 to 3, where 0=no blood seen, 3=blood alone passed). Total MMS score is sum of all sub-scores and ranges from 0 to 9, with higher scores indicating higher disease activity.

End point type	Secondary
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End point timeframe:

Week 12

APD: All randomized participants who received at least one dose of study drug and had MMS data at week 12.

End point values	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Induction Treatment Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	28	14	
Units: percentage of participants				
number (confidence interval 95%)	27.6 (11.3 to 43.9)	32.1 (14.8 to 49.4)	21.4 (0 to 42.9)	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (Induction Treatment Period) v Low dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.886
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.14
upper limit	10.16

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (Induction Treatment Period) v High dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.784
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.14
upper limit	4.18

Secondary: Percentage of Participants Who Achieved Symptomatic Response at Week 12

End point title	Percentage of Participants Who Achieved Symptomatic Response at Week 12
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End point description:

Symptomatic response is defined as a $\geq 30\%$ decrease from baseline in the composite clinical endpoint of the sum of MMS sub-scores of stool frequency and rectal bleeding. The MMS is a scoring system for assessment of UC and is composed of sub-scores of stool frequency (range: 0 to 3, where 0=normal

number of stools, 3=5 or more stools more than normal), endoscopy (range: 0 to 3, where 0=normal or inactive disease, 3=severe disease [spontaneous bleeding, ulceration]), rectal bleeding (range: 0 to 3, where 0=no blood seen, 3=blood alone passed). Total MMS score is sum of all sub-scores and ranges from 0 to 9, with higher scores indicating higher disease activity.

End point type	Secondary
End point timeframe:	
Week 12	
APD: All randomized participants who received at least one dose of study drug and had MMS data at week 12.	

End point values	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Induction Treatment Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	28	14	
Units: percentage of participants				
number (confidence interval 95%)	44.8 (26.7 to 62.9)	42.9 (24.5 to 61.2)	42.9 (16.9 to 68.8)	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (Induction Treatment Period) v Low dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.331
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	2.43

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (Induction Treatment Period) v High dose LY3471851 (Induction Treatment Period)

Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.407
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	2.52

Secondary: Percentage of Participants Who Achieved Histologic Remission at Week 12

End point title	Percentage of Participants Who Achieved Histologic Remission at Week 12
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End point description:

Histologic Remission is defined as Geboes score <2 or subscores = 0 for Grade 2a, 2b, 3, 4, and 5. The Geboes score is a 7-item instrument used to identify histologic changes in UC. The 7 items are Grade 0: Architectural changes (0=No abnormality to 3=Severe diffuse or multifocal abnormalities); Grade 1: Chronic inflammatory infiltrate (0=No increase to 3=Marked increase); Grade 2A: lamina propria eosinophils (0=No increase to 3=Marked increase); Grade 2B: lamina propria neutrophils (0= No increase to 3=Marked increase); Grade 3: Neutrophils in epithelium (0=None to 3=>50% crypts involved); Grade 4: Crypt destruction(0=none to 3=Unequivocal crypt destruction),and Grade 5: Erosion or ulceration:(0=No erosion, ulceration or granulation to 4=Ulcer or granulation tissue). The grade with severe histological observation is considered the Geboes score and ranges from 0 to 4, with higher scores indicating severe disease.

End point type	Secondary
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End point timeframe:

Week 12

APD: All randomized participants who received at least one dose of study drug and had Geboes data at week 12.

End point values	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Induction Treatment Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	28	14	
Units: percentage of participants				
number (confidence interval 95%)	10.3 (0.0 to 21.4)	7.1 (0.0 to 16.7)	7.1 (0.0 to 20.6)	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (Induction Treatment Period) v Low dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.564
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	6

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (Induction Treatment Period) v High dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.681
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk ratio (RR)
Point estimate	1.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.21
upper limit	10.97

Secondary: Percentage of Participants Who Achieved Histologic-Endoscopic Mucosal Healing (HEMH)

End point title	Percentage of Participants Who Achieved Histologic-Endoscopic Mucosal Healing (HEMH)
End point description:	
HEMH is defined as Geboes score <2 AND endoscopic remission. Geboes score is a 7-item instrument used to identify histologic changes in UC. The 7-items are Grade 0: Architectural changes (0=No abnormality to 3=Severe diffuse or multifocal abnormalities); Grade 1: Chronic inflammatory infiltrate (0=No increase to 3=Marked increase); Grade 2A: lamina propria eosinophils (0=No increase to 3=Marked increase); Grade 2B: lamina propria neutrophils (0= No increase to 3=Marked increase); Grade 3: Neutrophils in epithelium (0=None to 3=>50% crypts involved); Grade 4: Crypt destruction(0=none to 3=Unequivocal crypt destruction),and Grade 5: Erosion or ulceration:(0=No erosion, ulceration or granulation to 4=Ulcer or granulation tissue). The grade with severe histological observation is considered the Geboes score and ranges from 0 to 4, with higher scores indicating severe disease. Endoscopic remission is defined as achieving a MMS sub-score for endoscopy=0 or 1 (excluding friability).	
End point type	Secondary

End point timeframe:

Week 12

APD: All randomized participants who received at least one dose of study drug and had Geboes, MMS data at week 12.

End point values	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Induction Treatment Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	28	14	
Units: percentage of participants				
number (confidence interval 95%)	6.9 (0 to 16.1)	3.6 (0 to 10.4)	0 (0 to 0)	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (Induction Treatment Period) v Low dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.317
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	3.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	10.4

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (Induction Treatment Period) v High dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.238
Method	Cochran-Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	6.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	16.1

Secondary: Change from Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) - Total score

End point title	Change from Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) - Total score
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End point description:

IBDQ is a 32-item questionnaire that measures four aspects of participants' lives: symptoms directly related to the primary bowel disturbance (10 items), systemic symptoms (5 items), emotional function (12 items), and social function (5 items). Responses are graded on a 7-point Likert scale, where 7 denotes "not a problem at all" and 1 denotes "a very severe problem." The responses are summed to produce a total score ranging from 32 to 224, with higher score indicating a better quality of life. LS Mean was calculated using ANCOVA (analysis of covariance) model with treatment, baseline value, previous advanced therapy failure status (yes/no), baseline corticosteroid use (yes/no), baseline disease activity (MMS: [4 to 6] or [7 to 9]) and region (North America/Europe/Other) as fixed factors.

End point type	Secondary
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End point timeframe:

Baseline, Week 12

APD: All randomized participants who received at least one dose of study drug and had IBDQ data at baseline, week 12.

End point values	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Induction Treatment Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	26	13	
Units: score on a scale				
least squares mean (standard error)	25.76 (\pm 7.143)	36.42 (\pm 7.640)	26.71 (\pm 9.346)	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Low dose LY3471851 (Induction Treatment Period) v Placebo (Induction Treatment Period)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.378
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	9.71

Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.17
upper limit	31.6
Variability estimate	Standard error of the mean
Dispersion value	10.935

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (Induction Treatment Period) v High dose LY3471851 (Induction Treatment Period)
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.928
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.78
upper limit	19.88
Variability estimate	Standard error of the mean
Dispersion value	10.406

Secondary: Pharmacokinetics (PK): Trough Concentration of LY3471851 (Ctrough) at week 12

End point title	Pharmacokinetics (PK): Trough Concentration of LY3471851 (Ctrough) at week 12 ^[1]
End point description:	
C-trough is the concentration of drug in the blood immediately before the next dose was administered.	
End point type	Secondary
End point timeframe:	
Predose at 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: This outcome is specific to LY3471851 arms only.

End point values	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	26		
Units: microgram per milliliter (µg/mL)				
geometric mean (geometric coefficient	139 (± 105)	91.3 (± 49)		

of variation)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline to Follow-up (Up To Week 58)

Adverse event reporting additional description:

All randomized participants who received at least one dose of study drug.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.1
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Reporting groups

Reporting group title	High dose LY3471851 (Induction Treatment Period)
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Reporting group description: -

Reporting group title	Low dose LY3471851 (Induction Treatment Period)
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Reporting group description: -

Reporting group title	Placebo (Post-Treatment Follow-up Period)
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Reporting group description: -

Reporting group title	Placebo (Maintenance Treatment Period)
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Reporting group description: -

Reporting group title	High dose LY3471851 (Extension Treatment Period)
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Reporting group description: -

Reporting group title	High dose LY3471851 (Post-Treatment Follow-up Period)
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Reporting group description: -

Reporting group title	Low dose LY3471851 (Post-Treatment Follow-up Period)
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Reporting group description: -

Reporting group title	High dose LY3471851 (Maintenance Treatment Period)
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Reporting group description: -

Reporting group title	Placebo (Induction Treatment Period)
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Reporting group description: -

Reporting group title	Low dose LY3471851 (Maintenance Treatment Period)
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Reporting group description: -

Serious adverse events	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Post-Treatment Follow-up Period)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 32 (6.25%)	0 / 35 (0.00%)	0 / 11 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
lower limb fracture			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 32 (0.00%)	0 / 35 (0.00%)	0 / 11 (0.00%)
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			
syncope			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 32 (3.13%)	0 / 35 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
proctitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 32 (3.13%)	0 / 35 (0.00%)	0 / 11 (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
Infections and infestations			
vulval abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 32 (0.00%)	0 / 35 (0.00%)	0 / 11 (0.00%)
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	Placebo (Maintenance Treatment Period)	High dose LY3471851 (Extension Treatment Period)	High dose LY3471851 (Post- Treatment Follow-up Period)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	0 / 26 (0.00%)	0 / 25 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
lower limb fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 5 (0.00%)	0 / 26 (0.00%)	0 / 25 (0.00%)
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			

syncope alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 5 (0.00%) 0 / 0 0 / 0	0 / 26 (0.00%) 0 / 0 0 / 0	0 / 25 (0.00%) 0 / 0 0 / 0
Gastrointestinal disorders proctitis alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 5 (0.00%) 0 / 0 0 / 0	0 / 26 (0.00%) 0 / 0 0 / 0	0 / 25 (0.00%) 0 / 0 0 / 0
Infections and infestations vulval abscess alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 5 (0.00%) 0 / 0 0 / 0	0 / 26 (0.00%) 0 / 0 0 / 0	0 / 25 (0.00%) 0 / 0 0 / 0

Serious adverse events	Low dose LY3471851 (Post- Treatment Follow-up Period)	High dose LY3471851 (Maintenance Treatment Period)	Placebo (Induction Treatment Period)
Total subjects affected by serious adverse events subjects affected / exposed number of deaths (all causes) number of deaths resulting from adverse events	1 / 30 (3.33%) 0	0 / 8 (0.00%) 0	0 / 14 (0.00%) 0
Injury, poisoning and procedural complications lower limb fracture alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 30 (3.33%) 0 / 1 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 14 (0.00%) 0 / 0 0 / 0
Nervous system disorders syncope alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 30 (0.00%)	0 / 8 (0.00%)	0 / 14 (0.00%)
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			
proctitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 8 (0.00%)	0 / 14 (0.00%)
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			
vulval abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 8 (0.00%)	0 / 14 (0.00%)
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	Low dose LY3471851 (Maintenance Treatment Period)		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
lower limb fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
syncope			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

proctitis alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 10 (0.00%) 0 / 0 0 / 0		
Infections and infestations vulval abscess alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 10 (10.00%) 0 / 1 0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	High dose LY3471851 (Induction Treatment Period)	Low dose LY3471851 (Induction Treatment Period)	Placebo (Post- Treatment Follow-up Period)
Total subjects affected by non-serious adverse events subjects affected / exposed	20 / 32 (62.50%)	15 / 35 (42.86%)	1 / 11 (9.09%)
Investigations body temperature increased alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	4 / 32 (12.50%) 11	0 / 35 (0.00%) 0	0 / 11 (0.00%) 0
Injury, poisoning and procedural complications injection related reaction alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 35 (0.00%) 0	0 / 11 (0.00%) 0
Cardiac disorders extrasystoles alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 35 (0.00%) 0	0 / 11 (0.00%) 0
Nervous system disorders			

headache alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	4 / 32 (12.50%) 5	1 / 35 (2.86%) 1	0 / 11 (0.00%) 0
syncope alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 35 (0.00%) 0	0 / 11 (0.00%) 0
Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	2 / 35 (5.71%) 2	0 / 11 (0.00%) 0
neutropenia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 35 (2.86%) 2	0 / 11 (0.00%) 0
General disorders and administration site conditions application site reaction alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	2 / 35 (5.71%) 5	0 / 11 (0.00%) 0
hyperthermia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2	0 / 35 (0.00%) 0	0 / 11 (0.00%) 0
influenza like illness alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 35 (0.00%) 0	0 / 11 (0.00%) 0
injection site reaction alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	8 / 32 (25.00%) 21	6 / 35 (17.14%) 20	0 / 11 (0.00%) 0
malaise			

<p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 32 (0.00%)</p> <p>0</p>	<p>0 / 35 (0.00%)</p> <p>0</p>	<p>0 / 11 (0.00%)</p> <p>0</p>
<p>pyrexia</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>7 / 32 (21.88%)</p> <p>9</p>	<p>2 / 35 (5.71%)</p> <p>2</p>	<p>0 / 11 (0.00%)</p> <p>0</p>
<p>Gastrointestinal disorders</p> <p>abdominal pain</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>colitis ulcerative</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>nausea</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 32 (6.25%)</p> <p>2</p> <p>0 / 32 (0.00%)</p> <p>0</p> <p>2 / 32 (6.25%)</p> <p>3</p>	<p>0 / 35 (0.00%)</p> <p>0</p> <p>0 / 35 (0.00%)</p> <p>0</p> <p>0 / 35 (0.00%)</p> <p>0</p>	<p>0 / 11 (0.00%)</p> <p>0</p> <p>1 / 11 (9.09%)</p> <p>1</p> <p>0 / 11 (0.00%)</p> <p>0</p>
<p>Respiratory, thoracic and mediastinal disorders</p> <p>rhinorrhoea</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 32 (3.13%)</p> <p>1</p>	<p>0 / 35 (0.00%)</p> <p>0</p>	<p>0 / 11 (0.00%)</p> <p>0</p>
<p>Skin and subcutaneous tissue disorders</p> <p>acne</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>erythema</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>rosacea</p>	<p>0 / 32 (0.00%)</p> <p>0</p> <p>3 / 32 (9.38%)</p> <p>5</p>	<p>0 / 35 (0.00%)</p> <p>0</p> <p>1 / 35 (2.86%)</p> <p>3</p>	<p>0 / 11 (0.00%)</p> <p>0</p> <p>0 / 11 (0.00%)</p> <p>0</p>

alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 35 (0.00%) 0	0 / 11 (0.00%) 0
Musculoskeletal and connective tissue disorders arthritis alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) back pain alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) musculoskeletal stiffness alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) myalgia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0 0 / 32 (0.00%) 0 0 / 32 (0.00%) 0 2 / 32 (6.25%) 2	0 / 35 (0.00%) 0 0 / 35 (0.00%) 0 0 / 35 (0.00%) 0 0 / 35 (0.00%) 0	0 / 11 (0.00%) 0 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0
Infections and infestations erysipelas alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) covid-19 alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) influenza alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) nasopharyngitis alternative dictionary used:	0 / 32 (0.00%) 0 2 / 32 (6.25%) 2 0 / 32 (0.00%) 0	2 / 35 (5.71%) 3 3 / 35 (8.57%) 3 0 / 35 (0.00%) 0	0 / 11 (0.00%) 0 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0

MedDRA 25.1			
subjects affected / exposed	0 / 32 (0.00%)	0 / 35 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 32 (0.00%)	0 / 35 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 32 (0.00%)	0 / 35 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo (Maintenance Treatment Period)	High dose LY3471851 (Extension Treatment Period)	High dose LY3471851 (Post- Treatment Follow-up Period)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 5 (20.00%)	5 / 26 (19.23%)	0 / 25 (0.00%)
Investigations			
body temperature increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 5 (0.00%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
injection related reaction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 5 (0.00%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
extrasystoles			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 5 (0.00%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 25.1			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>syncope</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>1 / 5 (20.00%)</p> <p>1</p>	<p>0 / 26 (0.00%)</p> <p>0</p> <p>0 / 26 (0.00%)</p> <p>0</p>	<p>0 / 25 (0.00%)</p> <p>0</p> <p>0 / 25 (0.00%)</p> <p>0</p>
<p>Blood and lymphatic system disorders</p> <p>anaemia</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>neutropenia</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p>	<p>2 / 26 (7.69%)</p> <p>2</p> <p>0 / 26 (0.00%)</p> <p>0</p>	<p>0 / 25 (0.00%)</p> <p>0</p> <p>0 / 25 (0.00%)</p> <p>0</p>
<p>General disorders and administration site conditions</p> <p>application site reaction</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>hyperthermia</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>influenza like illness</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>injection site reaction</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>malaise</p> <p>alternative dictionary used: MedDRA 25.1</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p>	<p>0 / 26 (0.00%)</p> <p>0</p> <p>0 / 26 (0.00%)</p> <p>0</p> <p>0 / 26 (0.00%)</p> <p>0</p> <p>2 / 26 (7.69%)</p> <p>9</p>	<p>0 / 25 (0.00%)</p> <p>0</p> <p>0 / 25 (0.00%)</p> <p>0</p> <p>0 / 25 (0.00%)</p> <p>0</p>

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pyrexia</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p>	<p>0 / 26 (0.00%)</p> <p>0</p> <p>0 / 26 (0.00%)</p> <p>0</p>	<p>0 / 25 (0.00%)</p> <p>0</p> <p>0 / 25 (0.00%)</p> <p>0</p>
<p>Gastrointestinal disorders</p> <p>abdominal pain</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>colitis ulcerative</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>nausea</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p>	<p>0 / 26 (0.00%)</p> <p>0</p> <p>0 / 26 (0.00%)</p> <p>0</p> <p>0 / 26 (0.00%)</p> <p>0</p>	<p>0 / 25 (0.00%)</p> <p>0</p> <p>0 / 25 (0.00%)</p> <p>0</p> <p>0 / 25 (0.00%)</p> <p>0</p>
<p>Respiratory, thoracic and mediastinal disorders</p> <p>rhinorrhoea</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p>	<p>0 / 26 (0.00%)</p> <p>0</p>	<p>0 / 25 (0.00%)</p> <p>0</p>
<p>Skin and subcutaneous tissue disorders</p> <p>acne</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>erythema</p> <p>alternative dictionary used: MedDRA 25.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>rosacea</p> <p>alternative dictionary used: MedDRA 25.1</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p>	<p>0 / 26 (0.00%)</p> <p>0</p> <p>0 / 26 (0.00%)</p> <p>0</p>	<p>0 / 25 (0.00%)</p> <p>0</p> <p>0 / 25 (0.00%)</p> <p>0</p>

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
Musculoskeletal and connective tissue disorders			
arthritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
back pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
myalgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
Infections and infestations			
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	2 / 26 (7.69%) 2	0 / 25 (0.00%) 0
influenza			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 26 (0.00%) 0	0 / 25 (0.00%) 0
nasopharyngitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 5 (20.00%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
tonsillitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 5 (20.00%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 5 (0.00%)	0 / 26 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Low dose LY3471851 (Post- Treatment Follow-up Period)	High dose LY3471851 (Maintenance Treatment Period)	Placebo (Induction Treatment Period)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 30 (3.33%)	4 / 8 (50.00%)	5 / 14 (35.71%)
Investigations			
body temperature increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 8 (12.50%)	0 / 14 (0.00%)
occurrences (all)	0	3	0
Injury, poisoning and procedural complications			
injection related reaction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 8 (12.50%)	0 / 14 (0.00%)
occurrences (all)	0	10	0
Cardiac disorders			
extrasystoles			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 8 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 8 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

syncope alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	0 / 8 (0.00%) 0	0 / 14 (0.00%) 0
Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) neutropenia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0 0 / 30 (0.00%) 0	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	1 / 14 (7.14%) 1 1 / 14 (7.14%) 1
General disorders and administration site conditions application site reaction alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) hyperthermia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) influenza like illness alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) injection site reaction alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) malaise alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) pyrexia	0 / 30 (0.00%) 0 0 / 30 (0.00%) 0 0 / 30 (0.00%) 0 0 / 30 (0.00%) 0 0 / 30 (0.00%) 0	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 1 / 8 (12.50%) 12 1 / 8 (12.50%) 1	0 / 14 (0.00%) 0 0 / 14 (0.00%) 0 0 / 14 (0.00%) 0 0 / 14 (0.00%) 0

alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	2 / 8 (25.00%) 4	1 / 14 (7.14%) 1
Gastrointestinal disorders abdominal pain alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) colitis ulcerative alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) nausea alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0 0 / 30 (0.00%) 0 0 / 30 (0.00%) 0	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	0 / 14 (0.00%) 0 0 / 14 (0.00%) 0 0 / 14 (0.00%) 0
Respiratory, thoracic and mediastinal disorders rhinorrhoea alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	0 / 8 (0.00%) 0	1 / 14 (7.14%) 1
Skin and subcutaneous tissue disorders acne alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) erythema alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) rosacea alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0 0 / 30 (0.00%) 0 0 / 30 (0.00%) 0	1 / 8 (12.50%) 5 0 / 8 (0.00%) 0 1 / 8 (12.50%) 1	0 / 14 (0.00%) 0 0 / 14 (0.00%) 0 0 / 14 (0.00%) 0
Musculoskeletal and connective tissue			

disorders			
arthritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 8 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
back pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 8 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
musculoskeletal stiffness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 8 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
myalgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 8 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 8 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	1 / 8 (12.50%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
influenza			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 8 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 30 (3.33%)	1 / 8 (12.50%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
tonsillitis			

alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	0 / 8 (0.00%) 0	0 / 14 (0.00%) 0
Metabolism and nutrition disorders decreased appetite alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	0 / 8 (0.00%) 0	1 / 14 (7.14%) 1

Non-serious adverse events	Low dose LY3471851 (Maintenance Treatment Period)		
Total subjects affected by non-serious adverse events subjects affected / exposed	6 / 10 (60.00%)		
Investigations body temperature increased alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Injury, poisoning and procedural complications injection related reaction alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 12		
Cardiac disorders extrasystoles alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Nervous system disorders headache alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) syncope alternative dictionary used: MedDRA 25.1	0 / 10 (0.00%) 0		

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) neutropenia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1 0 / 10 (0.00%) 0		
General disorders and administration site conditions application site reaction alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) hyperthermia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) influenza like illness alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) injection site reaction alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) malaise alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) pyrexia alternative dictionary used: MedDRA 25.1	1 / 10 (10.00%) 6 0 / 10 (0.00%) 0 1 / 10 (10.00%) 4 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 pyrexia alternative dictionary used: MedDRA 25.1		

subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Gastrointestinal disorders abdominal pain alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) colitis ulcerative alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) nausea alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders rhinorrhoea alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Skin and subcutaneous tissue disorders acne alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) erythema alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all) rosacea alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0		
Musculoskeletal and connective tissue disorders			

arthritis alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
back pain alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
musculoskeletal stiffness alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
myalgia alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Infections and infestations erysipelas alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
covid-19 alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
influenza alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
nasopharyngitis alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
tonsillitis alternative dictionary used: MedDRA 25.1			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		
Metabolism and nutrition disorders decreased appetite alternative dictionary used: MedDRA 25.1 subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 November 2020	Amendment (a): Modified the study entry criteria in response to Food and Drug Administration (FDA) feedback.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported