



Clinical trial results:

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Evaluate the Efficacy and Safety of LY3375880 in Adult Subjects with Moderate-to-Severe Atopic Dermatitis

Summary

EudraCT number	2018-002401-56
Trial protocol	HU AT FR ES DE IT
Global end of trial date	27 February 2020

Results information

Result version number	v1 (current)
This version publication date	28 February 2021
First version publication date	28 February 2021

Trial information

Trial identification

Sponsor protocol code	I9N-MC-FCAB
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03831191
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 17104

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559,

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	27 February 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	27 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The reason for this study is to see if the study drug LY3375880 is safe and effective in adults with moderate-to-severe atopic dermatitis (AD).

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	12 February 2019
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: 17
Country: Number of subjects enrolled	Austria: 7
Country: Number of subjects enrolled	Canada: 4
Country: Number of subjects enrolled	France: 4
Country: Number of subjects enrolled	Hungary: 5
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Japan: 41
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	United States: 48
Worldwide total number of subjects	136
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)	128
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

Responders are participants who achieved a 50% reduction in the Eczema Area and Severity Index score [EASI-50] response, regardless of whether rescue therapy had been initiated during induction period. Participants did not receive 300 mg because the trial was stopped early.

Period 1

Period 1 title	Induction Period (16 Weeks)
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	Placebo

Arm description:

Induction Period:

Participants received placebo administered subcutaneously (SC) every 4 weeks (Q4W).

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:

Administered SC

Arm title	50 mg LY3375880
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Arm description:

Induction Period:

Participants received 50 milligrams (mg) LY3375880 administered SC Q4W.

Arm type	Experimental
Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC

Arm title	150 mg LY3375880
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Arm description:

Induction Period:

Participants received 150 mg LY3375880 administered SC Q4W.

Arm type	Experimental
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Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered SC	
Arm title	600 mg LY3375880

Arm description:

Induction Period:

Participants received 600 mg LY3375880 administered SC Q4W.

Arm type	Experimental
Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC

Number of subjects in period 1	Placebo	50 mg LY3375880	150 mg LY3375880
Started	33	35	34
Received at least one dose of study drug	33	35	34
Completed	10	14	13
Not completed	23	21	21
Consent withdrawn by subject	7	2	1
Adverse event, non-fatal	2	1	3
Pregnancy	-	-	1
Sponsor Decision	-	-	-
Study Terminated by Sponsor	12	15	16
Lack of efficacy	2	3	-
Protocol deviation	-	-	-

Number of subjects in period 1	600 mg LY3375880
Started	34
Received at least one dose of study drug	33
Completed	11
Not completed	23
Consent withdrawn by subject	3
Adverse event, non-fatal	4
Pregnancy	-
Sponsor Decision	1
Study Terminated by Sponsor	13

Lack of efficacy	-
Protocol deviation	2

Period 2

Period 2 title	Maintenance Period (36 Weeks)
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	Placebo Responder to Placebo/300 mg LY3375880

Arm description:

Maintenance Period:

Participants received placebo administered SC Q4W until loss of response then 300 mg LY3375880 SC Q4W .

Participants had received placebo SC Q4W during the induction period.

Arm type	Experimental
Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC

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

Dosage and administration details:

Administered SC .

Arm title	Placebo Non-Responder to 300 mg LY3375880
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Arm description:

Maintenance Period:

Participants received 300 mg LY3375880 administered SC Q4W.

Participants had received placebo SC Q4W during the induction period.

Arm type	Experimental
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Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered SC.	
Arm title	50 mg Responder to Placebo/50 mg LY3375880

Arm description:

Maintenance Period:

Participants received placebo administered SC Q4W until loss of response then 50 mg LY3375880 SC Q4W.

Participants had received 50 mg LY3375880 SC Q4W during the induction period.

Arm type	Experimental
Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC.

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

Dosage and administration details:

Administered SC.

Arm title	50 mg LY3375880 Responder to 50 mg LY3375880
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Arm description:

Maintenance Period:

Participants received 50 mg LY3375880 administered SC Q4W.

Participants had received 50 mg LY3375880 SC Q4W during the induction period.

Arm type	Experimental
Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC.

Arm title	50 mg LY3375880 Non-Responder to 150 mg LY3375880
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Arm description:

Maintenance Period:

Participants received 150 mg LY3375880 administered SC Q4W.

Participants had received 50 mg LY3375880 SC Q4W during the induction period.

Arm type	Experimental
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Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered SC.	
Arm title	150 mg Responder to Placebo/150 mg LY3375880

Arm description:

Maintenance Period:

Participants received placebo administered SC Q4W until loss of response then 150 mg LY3375880 SC Q4W.

Participants had received 150 mg LY3375880 SC Q4W during the induction period.

Arm type	Experimental
Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered SC.	
Arm title	150 mg LY3375880 Responder to 150 mg LY3375880

Arm description:

Maintenance Period:

Participants received 150 mg LY3375880 administered SC Q4W.

Participants had received 150 mg LY3375880 SC Q4W during the induction period.

Arm type	Experimental
Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered SC.	
Arm title	150 mg LY3375880 Non-Responder to 300 mg LY3375880

Arm description:

Maintenance Period:

Participants received 300 mg LY3375880 administered SC Q4W.

Participants had received 150 mg LY3375880 SC Q4W during the induction period.

Arm type	Experimental
Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered SC.	
Arm title	600 mg Responder to Placebo/600 mg LY3375880

Arm description:

Maintenance Period:

Participants received placebo administered SC Q4W until loss of response then 600 mg LY3375880 SC Q4W.

Participants had received 600 mg LY3375880 SC Q4W during the induction period.

Arm type	Experimental
Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC.

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

Dosage and administration details:

Administered SC.

Arm title	600 mg LY3375880 Responder to 600 mg LY3375880
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Arm description:

Maintenance Period:

Participants received 600 mg LY3375880 administered SC Q4W.

Participants had received 600 mg LY3375880 SC Q4W during the induction period.

Arm type	Experimental
Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC.

Arm title	600 mg LY3375880 Non-Responder to 600 mg LY3375880
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Arm description:

Maintenance Period:

Participants received 600 mg LY3375880 administered SC Q4W.

Participants had received 600 mg LY3375880 SC Q4W during the induction period.

Arm type	Experimental
Investigational medicinal product name	LY3375880
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC.

Number of subjects in period 2^[1]	Placebo Responder to Placebo/300 mg LY3375880	Placebo Non-Responder to 300 mg LY3375880	50 mg Responder to Placebo/50 mg LY3375880
Started	4	5	2
Completed	0	0	0
Not completed	4	5	2
Consent withdrawn by subject	-	-	-
Study Terminated by Sponsor	4	5	2
Lost to follow-up	-	-	-

Number of subjects in period 2^[1]	50 mg LY3375880 Responder to 50 mg LY3375880	50 mg LY3375880 Non-Responder to 150 mg LY3375880	150 mg Responder to Placebo/150 mg LY3375880
Started	4	8	1
Completed	0	0	0
Not completed	4	8	1
Consent withdrawn by subject	-	-	-
Study Terminated by Sponsor	4	8	1
Lost to follow-up	-	-	-

Number of subjects in period 2^[1]	150 mg LY3375880 Responder to 150 mg LY3375880	150 mg LY3375880 Non-Responder to 300 mg LY3375880	600 mg Responder to Placebo/600 mg LY3375880
Started	4	8	1
Completed	0	1	0
Not completed	4	7	1
Consent withdrawn by subject	-	-	-
Study Terminated by Sponsor	4	7	1
Lost to follow-up	-	-	-

Number of subjects in period 2^[1]	600 mg LY3375880 Responder to 600 mg LY3375880	600 mg LY3375880 Non-Responder to 600 mg LY3375880
Started	1	9
Completed	0	0
Not completed	1	9
Consent withdrawn by subject	-	2
Study Terminated by Sponsor	1	6
Lost to follow-up	-	1

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 were assigned to these arms during maintenance period.

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description:	
Induction Period:	
Participants received placebo administered subcutaneously (SC) every 4 weeks (Q4W).	
Reporting group title	50 mg LY3375880
Reporting group description:	
Induction Period:	
Participants received 50 milligrams (mg) LY3375880 administered SC Q4W.	
Reporting group title	150 mg LY3375880
Reporting group description:	
Induction Period:	
Participants received 150 mg LY3375880 administered SC Q4W.	
Reporting group title	600 mg LY3375880
Reporting group description:	
Induction Period:	
Participants received 600 mg LY3375880 administered SC Q4W.	

Reporting group values	Placebo	50 mg LY3375880	150 mg LY3375880
Number of subjects	33	35	34
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	37.00	37.70	39.50
standard deviation	± 14.98	± 16.00	± 13.94
Gender categorical			
Units: Subjects			
Female	11	16	17
Male	22	19	17
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	9	11	9
Not Hispanic or Latino	12	14	14
Unknown or Not Reported	12	10	11
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	11	14	10
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	2
White	19	19	20
More than one race	0	0	1
Unknown or Not Reported	2	1	1
Region of Enrollment			
Units: Subjects			

Argentina	5	3	5
Austria	0	4	1
Canada	0	0	3
France	2	1	1
Hungary	1	0	3
Italy	1	1	1
Spain	0	0	3
United States	14	15	7
Japan	10	11	10

Reporting group values	600 mg LY3375880	Total	
Number of subjects	34	136	
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	36.80		
standard deviation	± 13.84	-	
Gender categorical			
Units: Subjects			
Female	14	58	
Male	20	78	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	8	37	
Not Hispanic or Latino	16	56	
Unknown or Not Reported	10	43	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	1	
Asian	12	47	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	3	6	
White	19	77	
More than one race	0	1	
Unknown or Not Reported	0	4	
Region of Enrollment			
Units: Subjects			
Argentina	4	17	
Austria	2	7	
Canada	1	4	
France	0	4	
Hungary	1	5	
Italy	3	6	
Spain	1	4	
United States	12	48	
Japan	10	41	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Induction Period:	
Participants received placebo administered subcutaneously (SC) every 4 weeks (Q4W).	
Reporting group title	50 mg LY3375880
Reporting group description:	
Induction Period:	
Participants received 50 milligrams (mg) LY3375880 administered SC Q4W.	
Reporting group title	150 mg LY3375880
Reporting group description:	
Induction Period:	
Participants received 150 mg LY3375880 administered SC Q4W.	
Reporting group title	600 mg LY3375880
Reporting group description:	
Induction Period:	
Participants received 600 mg LY3375880 administered SC Q4W.	
Reporting group title	Placebo Responder to Placebo/300 mg LY3375880
Reporting group description:	
Maintenance Period:	
Participants received placebo administered SC Q4W until loss of response then 300 mg LY3375880 SC Q4W .	
Participants had received placebo SC Q4W during the induction period.	
Reporting group title	Placebo Non-Responder to 300 mg LY3375880
Reporting group description:	
Maintenance Period:	
Participants received 300 mg LY3375880 administered SC Q4W.	
Participants had received placebo SC Q4W during the induction period.	
Reporting group title	50 mg Responder to Placebo/50 mg LY3375880
Reporting group description:	
Maintenance Period:	
Participants received placebo administered SC Q4W until loss of response then 50 mg LY3375880 SC Q4W.	
Participants had received 50 mg LY3375880 SC Q4W during the induction period.	
Reporting group title	50 mg LY3375880 Responder to 50 mg LY3375880
Reporting group description:	
Maintenance Period:	
Participants received 50 mg LY3375880 administered SC Q4W.	
Participants had received 50 mg LY3375880 SC Q4W during the induction period.	
Reporting group title	50 mg LY3375880 Non-Responder to 150 mg LY3375880
Reporting group description:	
Maintenance Period:	
Participants received 150 mg LY3375880 administered SC Q4W.	
Participants had received 50 mg LY3375880 SC Q4W during the induction period.	
Reporting group title	150 mg Responder to Placebo/150 mg LY3375880
Reporting group description:	
Maintenance Period:	
Participants received placebo administered SC Q4W until loss of response then 150 mg LY3375880 SC Q4W.	

Participants had received 150 mg LY3375880 SC Q4W during the induction period.

Reporting group title	150 mg LY3375880 Responder to 150 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received 150 mg LY3375880 administered SC Q4W.

Participants had received 150 mg LY3375880 SC Q4W during the induction period.

Reporting group title	150 mg LY3375880 Non-Responder to 300 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received 300 mg LY3375880 administered SC Q4W.

Participants had received 150 mg LY3375880 SC Q4W during the induction period.

Reporting group title	600 mg Responder to Placebo/600 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received placebo administered SC Q4W until loss of response then 600 mg LY3375880 SC Q4W.

Participants had received 600 mg LY3375880 SC Q4W during the induction period.

Reporting group title	600 mg LY3375880 Responder to 600 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received 600 mg LY3375880 administered SC Q4W.

Participants had received 600 mg LY3375880 SC Q4W during the induction period.

Reporting group title	600 mg LY3375880 Non-Responder to 600 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received 600 mg LY3375880 administered SC Q4W.

Participants had received 600 mg LY3375880 SC Q4W during the induction period.

Subject analysis set title	300 mg LY3375880
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received 300 mg LY3375880 administered SC Q4W.

Primary: Percentage of Participants Achieving Validated Investigator's Global Assessment for AD (vIGA-AD) of 0 or 1 with a ≥ 2 Point Improvement

End point title	Percentage of Participants Achieving Validated Investigator's Global Assessment for AD (vIGA-AD) of 0 or 1 with a ≥ 2 Point Improvement
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End point description:

vIGA-AD measures participants' overall severity of their atopic dermatitis (AD), based on a static, numeric 5 point scale from 0 (clear) to 4 (severe). Higher scores indicate greater severity. The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. Non-responder imputation (NRI) method was used to impute missing data.

Analysis Population Description (APD): Induction Period; All randomized participants who completed or discontinued the study prior to study termination by the sponsor.

End point type	Primary
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End point timeframe:

Week 16

End point values	Placebo	50 mg LY3375880	150 mg LY3375880	600 mg LY3375880
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	17	21
Units: Percentage of participants				
number (confidence interval 95%)	9.5 (2.7 to 28.9)	5.0 (0.9 to 23.6)	5.9 (1.0 to 27.0)	4.8 (0.8 to 22.7)

Statistical analyses

Statistical analysis title	% of Participants Achieving vIGA-AD) of 0 or 1
Statistical analysis description: % of Participants Achieving vIGA-AD) of 0 or 1 With a ≥ 2 Point Improvement.	
Comparison groups	Placebo v 50 mg LY3375880
Number of subjects included in analysis	41
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.638
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	6.81

Statistical analysis title	% of Participants Achieving vIGA-AD) of 0 or 1
Statistical analysis description: % of Participants Achieving vIGA-AD) of 0 or 1 With a ≥ 2 Point Improvement.	
Comparison groups	Placebo v 150 mg LY3375880
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.773
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.05
upper limit	8.76

Statistical analysis title	% of Participants Achieving vIGA-AD) of 0 or 1
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Statistical analysis description:

% of Participants Achieving vIGA-AD) of 0 or 1 With a ≥ 2 Point Improvement.

Comparison groups	Placebo v 600 mg LY3375880
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.671
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.05
upper limit	7.26

Secondary: Percentage of Participants Achieving Eczema Area and Severity Index 75 (EASI-75)

End point title	Percentage of Participants Achieving Eczema Area and Severity Index 75 (EASI-75)
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End point description:

EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs - by scoring the extent of disease (percentage of skin affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100%) and the severity of 4 clinical signs (erythema, edema/papulation, excoriation, and lichenification) each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head and neck, trunk, upper limbs, and lower limbs). Half scores are allowed. Each body site will have a score that ranges from 0 to 72, and the final EASI score will be obtained by weight-averaging these 4 scores. Hence, the final EASI score will range from 0 to 72 (severe) for each time point. A higher score represented greater disease severity. The EASI75 is defined as a $\geq 75\%$ improvement from baseline in the EASI score. Non-responder imputation (NRI) method was used to impute missing data.

End point type	Secondary
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End point timeframe:

Week 16

APD: Induction Period; All randomized participants who completed or discontinued the study prior to study termination by the sponsor.

End point values	Placebo	50 mg LY3375880	150 mg LY3375880	600 mg LY3375880
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	17	21
Units: Percentage of Participants				
number (confidence interval 95%)	19.0 (7.7 to 40.0)	15.0 (5.2 to 36.0)	23.5 (9.6 to 47.3)	0.0 (0.0 to 15.5)

Statistical analyses

Statistical analysis title	Percentage of Participants Achieving EASI-75
Comparison groups	Placebo v 50 mg LY3375880
Number of subjects included in analysis	41
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999
Method	Fisher exact
Parameter estimate	Risk difference (RD)
Point estimate	-4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.2
upper limit	19.9

Statistical analysis title	Percentage of Participants Achieving EASI-75
Comparison groups	Placebo v 150 mg LY3375880
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999
Method	Fisher exact
Parameter estimate	Risk difference (RD)
Point estimate	4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.7
upper limit	30.8

Statistical analysis title	Percentage of Participants Achieving EASI-75
Comparison groups	Placebo v 600 mg LY3375880
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.107
Method	Fisher exact
Parameter estimate	Risk difference (RD)
Point estimate	-19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40
upper limit	0.2

Secondary: Percentage of Participants Achieving SCORing Atopic Dermatitis 75 (SCORAD-75)

End point title	Percentage of Participants Achieving SCORing Atopic Dermatitis 75 (SCORAD-75)
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End point description:

The SCORAD index uses the rule of nines to assess disease extent (head and neck 9%; upper limbs 9% each; lower limbs 18% each; anterior trunk 18%; back 18%; and genitals 1%). It evaluates 6 clinical characteristics to determine disease severity: (1) erythema, (2) edema/papulation, (3) oozing/crusts, (4) excoriation, (5) lichenification, and (6) dryness on a scale of 0 to 3 (0=absence, 1=mild, 2=moderate, 3=severe). The SCORAD index also assesses subjective symptoms of pruritus and sleep loss in the last 72 hours on visual analogue scales (VAS) of 0 to 10 where 0 is no itch or sleep loss and 10 is worst imaginable itch or sleep loss. These 3 aspects: extent of disease, disease severity, and subjective symptoms combine to give a score between 0(no disease) and 103 (severe disease). Higher scores indicate greater severity. Non-responder imputation (NRI) method was used to impute missing data.

End point type	Secondary
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End point timeframe:

Week 16

APD: Induction Period; All randomized participants who completed or discontinued the study prior to study termination by the sponsor.

End point values	Placebo	50 mg LY3375880	150 mg LY3375880	600 mg LY3375880
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	17	21
Units: Percentage of participants				
number (confidence interval 95%)	4.8 (0.8 to 22.7)	5.0 (0.9 to 23.6)	0.0 (0.0 to 18.4)	0.0 (0.0 to 15.5)

Statistical analyses

Statistical analysis title	Percentage of Participants Achieving SCORAD-75
Comparison groups	Placebo v 50 mg LY3375880
Number of subjects included in analysis	41
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999
Method	Fisher exact
Parameter estimate	Risk difference (RD)
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.1
upper limit	19.3

Statistical analysis title	Percentage of Participants Achieving SCORAD-75
Comparison groups	Placebo v 150 mg LY3375880
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999
Method	Fisher exact
Parameter estimate	Risk difference (RD)
Point estimate	-4.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.7
upper limit	14.1

Statistical analysis title	Percentage of Participants Achieving SCORAD-75
Comparison groups	Placebo v 600 mg LY3375880
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999
Method	Fisher exact
Parameter estimate	Risk difference (RD)
Point estimate	-4.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.7
upper limit	11.2

Secondary: Percentage of Participants Achieving vIGA-AD of 0

End point title	Percentage of Participants Achieving vIGA-AD of 0
End point description:	
vIGA-AD measures participants overall severity of their atopic dermatitis (AD), based on a static, numeric 5 point scale from 0 (clear) to 4 (severe). Higher scores indicate greater severity. The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. Non-responder imputation (NRI) method was used to impute missing data.	
APD: Induction Period; All randomized participants who completed or discontinued the study prior to study termination by the sponsor.	
End point type	Secondary
End point timeframe:	
Week 16	

End point values	Placebo	50 mg LY3375880	150 mg LY3375880	600 mg LY3375880
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	17	21
Units: Percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)

Statistical analyses

Statistical analysis title	Percentage of Participants Achieving vIGA-AD of 0
Comparison groups	Placebo v 50 mg LY3375880
Number of subjects included in analysis	41
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Percentage of Participants Achieving vIGA-AD of 0
Comparison groups	Placebo v 150 mg LY3375880
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Percentage of Participants Achieving vIGA-AD of 0
Comparison groups	Placebo v 600 mg LY3375880

Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Secondary: Mean Change from Baseline in Eczema Area and Severity Index (EASI) Score

End point title	Mean Change from Baseline in Eczema Area and Severity Index (EASI) Score
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End point description:

EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis-disease extent and clinical signs-by scoring the extent of disease(percentage of skin affected: 0= 0%;1 =1-9%; 2 =10-29%;3 = 30-49%;4 = 50-69%;5 = 70-89%;6 = 90-100%) and the severity of 4 clinical signs (erythema,edema/papulation,excoriation,and lichenification) each on a scale of 0 to 3(0= none,absent;1 =mild;2 = moderate;3=severe) at 4 body sites(head and neck,trunk,upper limbs,and lower limbs).Half scores are allowed.Each body site will have a score that ranges from 0 to 72,and the final EASI score will be obtained by weight-averaging these 4 scores.Hence,the final EASI score will range from 0 to 72(severe) for each time point.Higher scores indicate greater severity.Least Squares Mean(LS Means) were calculated using mixed model repeated measures(MMRM) model with treatment,region, baseline disease severity,visit,treatment-by-visit-interaction,baseline and baseline-by-visit-interaction as fixed

End point type	Secondary
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End point timeframe:

Baseline, Week 16

APD: Induction Period; All randomized participants who had a baseline and at least one post-baseline EASI value.

End point values	Placebo	50 mg LY3375880	150 mg LY3375880	600 mg LY3375880
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	8	8	9
Units: score on a scale				
least squares mean (standard error)	-11.45 (± 4.68)	-4.90 (± 4.30)	-5.89 (± 4.55)	-7.87 (± 4.02)

Statistical analyses

Statistical analysis title	Mean Change From Baseline in EASI Score
Comparison groups	Placebo v 50 mg LY3375880

Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.31
Method	Mixed models analysis
Parameter estimate	Median difference (net)
Point estimate	6.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.36
upper limit	19.45

Statistical analysis title	Mean Change From Baseline in EASI Score
Comparison groups	Placebo v 150 mg LY3375880
Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.393
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	5.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.5
upper limit	18.63

Statistical analysis title	Mean Change From Baseline in EASI Score
Comparison groups	Placebo v 600 mg LY3375880
Number of subjects included in analysis	15
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.564
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	3.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.91
upper limit	16.08

Secondary: Mean Change from Baseline in SCORAD

End point title	Mean Change from Baseline in SCORAD
End point description:	
<p>The SCORAD index uses the rule of nines to assess disease extent (head and neck 9%;upper limbs 9% each;lower limbs 18% each;anterior trunk 18%;back 18%;and genitals 1%).It evaluates 6 clinical characteristics to determine disease severity: (1)erythema,(2)edema/papulation, (3)oozing/crusts,(4) excoriation,(5) lichenification, and (6) dryness on a scale of 0 to 3(0=absence,1=mild,2=moderate,3=severe).The SCORAD index also assesses subjective symptoms of pruritus and sleep loss in the last 72 hours on visual analogue scales(VAS) of 0 to 10 where 0 is no itch or sleep loss and 10 is worst imaginable itch or sleep loss.These 3 aspects: extent of disease,disease severity,and subjective symptoms combine to give a score between 0(no disease) and 103(severe disease).Higher scores indicate greater severity. LS Means were calculated using a MMRM model with treatment,region,baseline disease severity,visit, treatment-by-visit-interaction,baseline and baseline-by-visit-interaction as fixed effects.</p>	
End point type	Secondary
End point timeframe:	
Baseline, Week 16	
APD: Induction Period; All randomized participants who had a baseline and at least one post-baseline SCORAD value.	

End point values	Placebo	50 mg LY3375880	150 mg LY3375880	600 mg LY3375880
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	8	9
Units: score on a scale				
least squares mean (standard error)	-19.27 (± 5.92)	-11.66 (± 5.72)	-16.94 (± 6.03)	-12.75 (± 5.3)

Statistical analyses

Statistical analysis title	Mean Change from Baseline in SCORAD
Comparison groups	Placebo v 50 mg LY3375880
Number of subjects included in analysis	15
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.356
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	7.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.82
upper limit	24.05

Statistical analysis title	Mean Change from Baseline in SCORAD
Comparison groups	Placebo v 150 mg LY3375880

Number of subjects included in analysis	15
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.783
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	2.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.64
upper limit	19.3

Statistical analysis title	Mean Change from Baseline in SCORAD
Comparison groups	Placebo v 600 mg LY3375880
Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.414
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	6.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	22.43

Secondary: Percentage of Participants Achieving vIGA-AD of 0 or 1 with a ≥ 2 -point improvement at Week 52

End point title	Percentage of Participants Achieving vIGA-AD of 0 or 1 with a ≥ 2 -point improvement at Week 52
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End point description:

vIGA-AD measures participants overall severity of their atopic dermatitis (AD), based on a static, numeric 5 point scale from 0 (clear) to 4 (severe). Higher scores indicate greater severity. The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. Non-responder imputation (NRI) method was used to impute missing data.

APD: Maintenance Period; All randomized participants who had a ≥ 2 -point improvement at Week 52.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Placebo	50 mg LY3375880	150 mg LY3375880	600 mg LY3375880
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	4	12	10
Units: Percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 32.4)	0.0 (0.0 to 49.0)	0.0 (0.0 to 24.2)	0.0 (0.0 to 27.8)

End point values	300 mg LY3375880			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 22.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Area Under the Concentration Versus Time Curve at a steady state (AUC_{T,ss}) of LY3375880

End point title	Pharmacokinetics (PK): Area Under the Concentration Versus Time Curve at a steady state (AUC _{T,ss}) of LY3375880 ^[1]
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End point description:

Pharmacokinetics (PK): Area Under the Concentration Versus Time Curve at a steady state (AUC_{T,ss}) of LY3375880

APD: All randomized participants who received LY3375880 and had evaluable PK data.

Participants did not receive 300 mg because the trial was stopped early.

End point type	Secondary
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End point timeframe:

Induction Period: Pre-dose, Day 0, Day 7, Day 14, Day 28, Day 56, Day 112 Post-dose; Maintenance Period: Predose, Day 168; Day 252, Day 364 Post-dose

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: PK analysis exclude placebo arm.

End point values	50 mg LY3375880	150 mg LY3375880	600 mg LY3375880	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	34	33	
Units: Nanograms*hour per millilitre (ng*h/mL)				
geometric mean (geometric coefficient of variation)	4450 (± 80.2)	11200 (± 41.9)	49000 (± 40.5)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline Up To 45 Weeks

Adverse event reporting additional description:

All participants who received at least one dose of study drug. Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.1
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Reporting groups

Reporting group title	50 mg LY3375880
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Reporting group description:

Induction Period:

Participants received 50 mg LY3375880 administered SC Q4W.

Reporting group title	150 mg LY3375880
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Reporting group description:

Induction Period:

Participants received 150 mg LY3375880 administered SC Q4W.

Reporting group title	600 mg LY3375880
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Reporting group description:

Induction Period:

Participants received 600 mg LY3375880 administered SC Q4W.

Reporting group title	Placebo
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Reporting group description:

Induction Period:

Participants received placebo administered subcutaneously (SC) every 4 weeks (Q4W).

Reporting group title	50 mg LY3375880 Non-Responder to 150 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received 150 mg LY3375880 administered SC Q4W.

Participants had received 50 mg LY3375880 SC Q4W during the induction period.

Reporting group title	50 mg LY3375880 Responder to 50 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received 50 mg LY3375880 administered SC Q4W.

Participants had received 50 mg LY3375880 SC Q4W during the induction period.

Reporting group title	50 mg Responder to Placebo/50 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received placebo administered SC Q4W until loss of response then 50 mg LY3375880 SC Q4W.

Participants had received 50 mg LY3375880 SC Q4W during the induction period.

Reporting group title	150 mg LY3375880 Non-Responder to 300 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received 300 mg LY3375880 administered SC Q4W.

Participants had received 150 mg LY3375880 SC Q4W during the induction period.

Reporting group title	150 mg LY3375880 Responder to 150 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received 150 mg LY3375880 administered SC Q4W.

Participants had received 150 mg LY3375880 SC Q4W during the induction period.

Reporting group title	150 mg Responder to Placebo/150 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received placebo administered SC Q4W until loss of response then 150 mg LY3375880 SC Q4W.

Participants had received 150 mg LY3375880 SC Q4W during the induction period.

Reporting group title	600 mg LY3375880 Non-Responder to 600 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received 600 mg LY3375880 administered SC Q4W.

Participants had received 600 mg LY3375880 SC Q4W during the induction period.

Reporting group title	600 mg LY3375880 Responder to 600 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received 600 mg LY3375880 administered SC Q4W.

Participants had received 600 mg LY3375880 SC Q4W during the induction period.

Reporting group title	600 mg Responder to Placebo/600 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received placebo administered SC Q4W until loss of response then 600 mg LY3375880 SC Q4W.

Participants had received 600 mg LY3375880 SC Q4W during the induction period.

Reporting group title	Placebo Non-Responder to 300 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received 300 mg LY3375880 administered SC Q4W.

Participants had received placebo SC Q4W during the induction period.

Reporting group title	Placebo Responder to Placebo/300 mg LY3375880
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Reporting group description:

Maintenance Period:

Participants received placebo administered SC Q4W until loss of response then 300 mg LY3375880 SC Q4W .

Participants had received placebo SC Q4W during the induction period.

Reporting group title	50 mg LY3375880 Q4W Post-Treatment Follow-Up Period
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Reporting group description:

Follow-up: participants did not receive drug during the follow-up period.

Reporting group title	150 mg LY3375880 Q4W Post-Treatment Follow-Up Period
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Reporting group description:

Follow-up: participants did not receive drug during the follow-up period.

Reporting group title	600 mg LY3375880 Q4W Post-Treatment Follow-Up Period
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Reporting group description:

Follow-up: participants did not receive drug during the follow-up period.

Reporting group title	Placebo Post-Treatment Follow-Up Period
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Reporting group description:

Follow-up: participants did not receive drug during the follow-up period.

Serious adverse events	50 mg LY3375880	150 mg LY3375880	600 mg LY3375880
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 35 (0.00%)	0 / 34 (0.00%)	2 / 33 (6.06%)
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)			
lung adenocarcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 35 (0.00%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
cardiac arrest			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 35 (0.00%)	0 / 34 (0.00%)	0 / 33 (0.00%)
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			
dermatitis atopic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 35 (0.00%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo	50 mg LY3375880 Non-Responder to 150 mg LY3375880	50 mg LY3375880 Responder to 50 mg LY3375880
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 33 (0.00%)	0 / 8 (0.00%)	0 / 4 (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) lung adenocarcinoma alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 33 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 4 (0.00%) 0 / 0 0 / 0
Cardiac disorders cardiac arrest alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 33 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 4 (0.00%) 0 / 0 0 / 0
Skin and subcutaneous tissue disorders dermatitis atopic alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 33 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 4 (0.00%) 0 / 0 0 / 0

Serious adverse events	50 mg Responder to Placebo/50 mg LY3375880	150 mg LY3375880 Non-Responder to 300 mg LY3375880	150 mg LY3375880 Responder to 150 mg LY3375880
Total subjects affected by serious adverse events subjects affected / exposed number of deaths (all causes) number of deaths resulting from adverse events	0 / 2 (0.00%) 0 0	0 / 8 (0.00%) 0 0	0 / 4 (0.00%) 0 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) lung adenocarcinoma alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 2 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 4 (0.00%) 0 / 0 0 / 0
Cardiac disorders cardiac arrest alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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 dermatitis atopic alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 2 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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	150 mg Responder to Placebo/150 mg LY3375880	600 mg LY3375880 Non-Responder to 600 mg LY3375880	600 mg LY3375880 Responder to 600 mg LY3375880
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 9 (0.00%)	0 / 1 (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) lung adenocarcinoma alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 9 (0.00%)	0 / 1 (0.00%)
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 cardiac arrest alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 9 (0.00%)	0 / 1 (0.00%)
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 dermatitis atopic alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 9 (0.00%)	0 / 1 (0.00%)
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	600 mg Responder to Placebo/600 mg LY3375880	Placebo Non-Responder to 300 mg LY3375880	Placebo Responder to Placebo/300 mg LY3375880
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 4 (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)			
lung adenocarcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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			
cardiac arrest			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
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	50 mg LY3375880 Q4W Post-Treatment Follow-Up Period	150 mg LY3375880 Q4W Post-Treatment Follow-Up Period	600 mg LY3375880 Q4W Post-Treatment Follow-Up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 3 (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)			
lung adenocarcinoma			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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			
cardiac arrest			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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			
dermatitis atopic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 Post-Treatment Follow-Up Period		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
lung adenocarcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
cardiac arrest			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			

dermatitis atopic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	50 mg LY3375880	150 mg LY3375880	600 mg LY3375880
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 35 (25.71%)	12 / 34 (35.29%)	12 / 33 (36.36%)
General disorders and administration site conditions			
injection site pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 35 (0.00%)	0 / 34 (0.00%)	2 / 33 (6.06%)
occurrences (all)	0	0	4
injection site reaction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 35 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	2	0
Reproductive system and breast disorders			
menstruation irregular			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed ^[1]	1 / 16 (6.25%)	0 / 17 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 35 (0.00%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
pneumonitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 35 (0.00%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0

<p>Psychiatric disorders</p> <p>depression</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 35 (2.86%)</p> <p>1</p>	<p>0 / 34 (0.00%)</p> <p>0</p>	<p>0 / 33 (0.00%)</p> <p>0</p>
<p>insomnia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 35 (2.86%)</p> <p>1</p>	<p>4 / 34 (11.76%)</p> <p>4</p>	<p>1 / 33 (3.03%)</p> <p>1</p>
<p>Investigations</p> <p>alanine aminotransferase increased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 35 (0.00%)</p> <p>0</p>	<p>0 / 34 (0.00%)</p> <p>0</p>	<p>1 / 33 (3.03%)</p> <p>1</p>
<p>aspartate aminotransferase increased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 35 (0.00%)</p> <p>0</p>	<p>0 / 34 (0.00%)</p> <p>0</p>	<p>2 / 33 (6.06%)</p> <p>2</p>
<p>electrocardiogram qt prolonged</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 35 (0.00%)</p> <p>0</p>	<p>0 / 34 (0.00%)</p> <p>0</p>	<p>0 / 33 (0.00%)</p> <p>0</p>
<p>Injury, poisoning and procedural complications</p> <p>ligament rupture</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 35 (0.00%)</p> <p>0</p>	<p>0 / 34 (0.00%)</p> <p>0</p>	<p>0 / 33 (0.00%)</p> <p>0</p>
<p>ligament sprain</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 35 (0.00%)</p> <p>0</p>	<p>0 / 34 (0.00%)</p> <p>0</p>	<p>0 / 33 (0.00%)</p> <p>0</p>
<p>meniscus injury</p> <p>alternative dictionary used: MedDRA 21.1</p>			

subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0	0 / 34 (0.00%) 0	0 / 33 (0.00%) 0
Cardiac disorders cardiac failure congestive alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0	0 / 34 (0.00%) 0	0 / 33 (0.00%) 0
cardiomyopathy alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0	0 / 34 (0.00%) 0	0 / 33 (0.00%) 0
Nervous system disorders headache alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	2 / 35 (5.71%) 2	0 / 34 (0.00%) 0	2 / 33 (6.06%) 2
hypoesthesia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0	0 / 34 (0.00%) 0	2 / 33 (6.06%) 2
Eye disorders cataract alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0	0 / 34 (0.00%) 0	1 / 33 (3.03%) 1
Gastrointestinal disorders gastroesophageal reflux disease alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0	0 / 34 (0.00%) 0	0 / 33 (0.00%) 0
Skin and subcutaneous tissue disorders androgenetic alopecia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0	0 / 34 (0.00%) 0	0 / 33 (0.00%) 0
dermatitis atopic			

<p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 35 (2.86%)</p> <p>1</p>	<p>3 / 34 (8.82%)</p> <p>4</p>	<p>3 / 33 (9.09%)</p> <p>3</p>
<p>pain of skin</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 35 (0.00%)</p> <p>0</p>	<p>0 / 34 (0.00%)</p> <p>0</p>	<p>2 / 33 (6.06%)</p> <p>2</p>
<p>pruritus</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 35 (2.86%)</p> <p>1</p>	<p>2 / 34 (5.88%)</p> <p>2</p>	<p>3 / 33 (9.09%)</p> <p>3</p>
<p>Musculoskeletal and connective tissue disorders</p> <p>synovial cyst</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 35 (0.00%)</p> <p>0</p>	<p>0 / 34 (0.00%)</p> <p>0</p>	<p>0 / 33 (0.00%)</p> <p>0</p>
<p>Infections and infestations</p> <p>cellulitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>folliculitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>nasopharyngitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>paronychia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>postoperative wound infection</p> <p>alternative dictionary used:</p>	<p>0 / 35 (0.00%)</p> <p>0</p> <p>1 / 35 (2.86%)</p> <p>1</p> <p>3 / 35 (8.57%)</p> <p>3</p> <p>0 / 35 (0.00%)</p> <p>0</p>	<p>0 / 34 (0.00%)</p> <p>0</p> <p>0 / 34 (0.00%)</p> <p>0</p> <p>1 / 34 (2.94%)</p> <p>1</p> <p>2 / 34 (5.88%)</p> <p>2</p>	<p>0 / 33 (0.00%)</p> <p>0</p> <p>0 / 33 (0.00%)</p> <p>0</p> <p>0 / 33 (0.00%)</p> <p>0</p> <p>0 / 33 (0.00%)</p> <p>0</p>

MedDRA 21.1			
subjects affected / exposed	1 / 35 (2.86%)	3 / 34 (8.82%)	1 / 33 (3.03%)
occurrences (all)	1	4	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 35 (0.00%)	1 / 34 (2.94%)	1 / 33 (3.03%)
occurrences (all)	0	1	1
Metabolism and nutrition disorders			
hypokalaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 35 (0.00%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo	50 mg LY3375880 Non-Responder to 150 mg LY3375880	50 mg LY3375880 Responder to 50 mg LY3375880
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 33 (21.21%)	2 / 8 (25.00%)	1 / 4 (25.00%)
General disorders and administration site conditions			
injection site pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 33 (3.03%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	6	0	0
injection site reaction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 33 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
menstruation irregular			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed ^[1]	0 / 11 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 21.1			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pneumonitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 33 (0.00%)</p> <p>0</p> <p>0 / 33 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p> <p>0 / 8 (0.00%)</p> <p>0</p>	<p>1 / 4 (25.00%)</p> <p>1</p> <p>0 / 4 (0.00%)</p> <p>0</p>
<p>Psychiatric disorders</p> <p>depression</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>insomnia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 33 (0.00%)</p> <p>0</p> <p>2 / 33 (6.06%)</p> <p>2</p>	<p>0 / 8 (0.00%)</p> <p>0</p> <p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>
<p>Investigations</p> <p>alanine aminotransferase increased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>aspartate aminotransferase increased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>electrocardiogram qt prolonged</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 33 (0.00%)</p> <p>0</p> <p>0 / 33 (0.00%)</p> <p>0</p> <p>0 / 33 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p> <p>0 / 8 (0.00%)</p> <p>0</p> <p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>
<p>Injury, poisoning and procedural complications</p> <p>ligament rupture</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ligament sprain</p> <p>alternative dictionary used:</p>	<p>0 / 33 (0.00%)</p> <p>0</p>	<p>1 / 8 (12.50%)</p> <p>1</p>	<p>0 / 4 (0.00%)</p> <p>0</p>

MedDRA 21.1			
subjects affected / exposed	0 / 33 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
meniscus injury			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 33 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
cardiac failure congestive			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 33 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
cardiomyopathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 33 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 33 (3.03%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 33 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 33 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 33 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

<p>androgenetic alopecia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 33 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>dermatitis atopic</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>3 / 33 (9.09%)</p> <p>3</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>pain of skin</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 33 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>pruritus</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 33 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Musculoskeletal and connective tissue disorders</p> <p>synovial cyst</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 33 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Infections and infestations</p> <p>cellulitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>folliculitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>nasopharyngitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>paronychia</p>	<p>0 / 33 (0.00%)</p> <p>0</p> <p>1 / 33 (3.03%)</p> <p>1</p> <p>0 / 33 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p> <p>1 / 8 (12.50%)</p> <p>1</p> <p>1 / 8 (12.50%)</p> <p>1</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>

alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
postoperative wound infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
upper respiratory tract infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Metabolism and nutrition disorders hypokalaemia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0

Non-serious adverse events	50 mg Responder to Placebo/50 mg LY3375880	150 mg LY3375880 Non-Responder to 300 mg LY3375880	150 mg LY3375880 Responder to 150 mg LY3375880
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 2 (50.00%)	3 / 8 (37.50%)	1 / 4 (25.00%)
General disorders and administration site conditions injection site pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
injection site reaction alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0	1 / 4 (25.00%) 4
Reproductive system and breast disorders menstruation irregular alternative dictionary used: MedDRA 21.1 subjects affected / exposed ^[1] occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0

Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) pneumonitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0	0 / 8 (0.00%) 0 1 / 8 (12.50%) 1	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0
Psychiatric disorders depression alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) insomnia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0	1 / 8 (12.50%) 1 0 / 8 (0.00%) 0	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0
Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) aspartate aminotransferase increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) electrocardiogram qt prolonged alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0
Injury, poisoning and procedural complications ligament rupture alternative dictionary used: MedDRA 21.1			

<p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>occurrences (all)</p> <p>0</p>		
<p>ligament sprain</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>occurrences (all)</p> <p>0</p>		
<p>meniscus injury</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>occurrences (all)</p> <p>0</p>		
<p>Cardiac disorders</p> <p>cardiac failure congestive</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>occurrences (all)</p> <p>0</p>		
<p>cardiomyopathy</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>occurrences (all)</p> <p>0</p>		
<p>Nervous system disorders</p> <p>headache</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>0</p>	<p>1 / 8 (12.50%)</p> <p>1</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>occurrences (all)</p> <p>0</p>		
<p>hypoaesthesia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>occurrences (all)</p> <p>0</p>		
<p>Eye disorders</p> <p>cataract</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>occurrences (all)</p> <p>0</p>		
<p>Gastrointestinal disorders</p>		

gastroesophageal reflux disease alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Skin and subcutaneous tissue disorders androgenetic alopecia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) dermatitis atopic alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) pain of skin alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) pruritus alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0
Musculoskeletal and connective tissue disorders synovial cyst alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Infections and infestations cellulitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) folliculitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0

nasopharyngitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
paronychia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
postoperative wound infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
upper respiratory tract infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Metabolism and nutrition disorders hypokalaemia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0

Non-serious adverse events	150 mg Responder to Placebo/150 mg LY3375880	600 mg LY3375880 Non-Responder to 600 mg LY3375880	600 mg LY3375880 Responder to 600 mg LY3375880
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 1 (100.00%)	2 / 9 (22.22%)	0 / 1 (0.00%)
General disorders and administration site conditions injection site pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 9 (0.00%) 0	0 / 1 (0.00%) 0
injection site reaction alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 9 (0.00%) 0	0 / 1 (0.00%) 0
Reproductive system and breast			

disorders menstruation irregular alternative dictionary used: MedDRA 21.1 subjects affected / exposed ^[1] occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) pneumonitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	0 / 9 (0.00%) 0 0 / 9 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0
Psychiatric disorders depression alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) insomnia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	0 / 9 (0.00%) 0 0 / 9 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0
Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) aspartate aminotransferase increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) electrocardiogram qt prolonged alternative dictionary used: MedDRA 21.1	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 	0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 9 (0.00%) 0	0 / 1 (0.00%) 0
Injury, poisoning and procedural complications ligament rupture alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 9 (0.00%) 0	0 / 1 (0.00%) 0
ligament sprain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 9 (11.11%) 1	0 / 1 (0.00%) 0
meniscus injury alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 9 (11.11%) 1	0 / 1 (0.00%) 0
Cardiac disorders cardiac failure congestive alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 9 (0.00%) 0	0 / 1 (0.00%) 0
cardiomyopathy alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 9 (0.00%) 0	0 / 1 (0.00%) 0
Nervous system disorders headache alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 9 (0.00%) 0	0 / 1 (0.00%) 0
hypoaesthesia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 9 (0.00%) 0	0 / 1 (0.00%) 0
Eye disorders			

cataract alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 9 (11.11%) 1	0 / 1 (0.00%) 0
Gastrointestinal disorders gastrooesophageal reflux disease alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 9 (0.00%) 0	0 / 1 (0.00%) 0
Skin and subcutaneous tissue disorders androgenetic alopecia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) dermatitis atopic alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) pain of skin alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) pruritus alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 0 / 9 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0
Musculoskeletal and connective tissue disorders synovial cyst alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 9 (11.11%) 1	0 / 1 (0.00%) 0
Infections and infestations cellulitis alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 9 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 9 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 9 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 9 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 1 (100.00%)	0 / 9 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 9 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
hypokalaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 9 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	600 mg Responder to Placebo/600 mg LY3375880	Placebo Non- Responder to 300 mg LY3375880	Placebo Responder to Placebo/300 mg LY3375880
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	4 / 5 (80.00%)	1 / 4 (25.00%)
General disorders and administration site conditions			
injection site pain			
alternative dictionary used: MedDRA 21.1			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>injection site reaction</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 1 (0.00%)</p> <p>0</p> <p>0 / 1 (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 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>
<p>Reproductive system and breast disorders</p> <p>menstruation irregular</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed^[1]</p> <p>occurrences (all)</p>	<p>0 / 1 (0.00%)</p> <p>0</p>	<p>0 / 2 (0.00%)</p> <p>0</p>	<p>0 / 2 (0.00%)</p> <p>0</p>
<p>Respiratory, thoracic and mediastinal disorders</p> <p>cough</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pneumonitis</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 1 (0.00%)</p> <p>0</p> <p>0 / 1 (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 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>
<p>Psychiatric disorders</p> <p>depression</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>insomnia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 1 (0.00%)</p> <p>0</p> <p>0 / 1 (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 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>
<p>Investigations</p> <p>alanine aminotransferase increased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>aspartate aminotransferase</p>	<p>0 / 1 (0.00%)</p> <p>0</p>	<p>1 / 5 (20.00%)</p> <p>1</p>	<p>0 / 4 (0.00%)</p> <p>0</p>

increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
electrocardiogram qt prolonged alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 5 (20.00%) 1	0 / 4 (0.00%) 0
Injury, poisoning and procedural complications ligament rupture alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
ligament sprain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
meniscus injury alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Cardiac disorders cardiac failure congestive alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 5 (20.00%) 1	0 / 4 (0.00%) 0
cardiomyopathy alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 5 (20.00%) 1	0 / 4 (0.00%) 0
Nervous system disorders headache alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0

hypoaesthesia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Eye disorders cataract alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Gastrointestinal disorders gastrooesophageal reflux disease alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 5 (20.00%) 1	0 / 4 (0.00%) 0
Skin and subcutaneous tissue disorders androgenetic alopecia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) dermatitis atopic alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) pain of skin alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) pruritus alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	1 / 5 (20.00%) 1 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0	0 / 4 (0.00%) 0 1 / 4 (25.00%) 1 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0
Musculoskeletal and connective tissue disorders synovial cyst alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
folliculitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
paronychia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
postoperative wound infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
hypokalaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
General disorders and administration site conditions injection site pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) injection site reaction alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0
Reproductive system and breast disorders menstruation irregular alternative dictionary used: MedDRA 21.1 subjects affected / exposed ^[1] occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) pneumonitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0
Psychiatric disorders depression alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) insomnia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0
Investigations			

alanine aminotransferase increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 3 (0.00%) 0
aspartate aminotransferase increased alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 3 (0.00%) 0
electrocardiogram qt prolonged alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 3 (0.00%) 0
Injury, poisoning and procedural complications ligament rupture alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 3 (0.00%) 0
ligament sprain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 3 (0.00%) 0
meniscus injury alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 3 (0.00%) 0
Cardiac disorders cardiac failure congestive alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 3 (0.00%) 0
cardiomyopathy alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 3 (0.00%) 0

<p>Nervous system disorders</p> <p>headache</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>
<p>hypoaesthesia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>
<p>Eye disorders</p> <p>cataract</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>
<p>Gastrointestinal disorders</p> <p>gastrooesophageal reflux disease</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>
<p>Skin and subcutaneous tissue disorders</p> <p>androgenetic alopecia</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>dermatitis atopic</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pain of skin</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pruritus</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 8 (0.00%)</p> <p>0</p> <p>0 / 8 (0.00%)</p> <p>0</p> <p>0 / 8 (0.00%)</p> <p>0</p> <p>0 / 8 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p>

Musculoskeletal and connective tissue disorders synovial cyst alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 3 (0.00%) 0
Infections and infestations cellulitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) folliculitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) nasopharyngitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) paronychia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) postoperative wound infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) upper respiratory tract infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0	0 / 8 (0.00%) 1 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 1 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0
Metabolism and nutrition disorders hypokalaemia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 3 (0.00%) 0

Non-serious adverse events	Placebo Post-Treatment Follow-Up Period		
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 8 (0.00%)		
General disorders and administration site conditions injection site pain alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) injection site reaction alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0		
Reproductive system and breast disorders menstruation irregular alternative dictionary used: MedDRA 21.1 subjects affected / exposed ^[1] occurrences (all)	0 / 1 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) pneumonitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0		
Psychiatric disorders depression alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) insomnia alternative dictionary used: MedDRA 21.1	0 / 8 (0.00%) 0		

<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 8 (0.00%)</p> <p>0</p>		
<p>Investigations</p> <p>alanine aminotransferase increased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>aspartate aminotransferase increased</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>electrocardiogram qt prolonged</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 8 (0.00%)</p> <p>0</p> <p>0 / 8 (0.00%)</p> <p>0</p> <p>0 / 8 (0.00%)</p> <p>0</p>		
<p>Injury, poisoning and procedural complications</p> <p>ligament rupture</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ligament sprain</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>meniscus injury</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 8 (0.00%)</p> <p>0</p> <p>0 / 8 (0.00%)</p> <p>0</p> <p>0 / 8 (0.00%)</p> <p>0</p>		
<p>Cardiac disorders</p> <p>cardiac failure congestive</p> <p>alternative dictionary used: MedDRA 21.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>cardiomyopathy</p> <p>alternative dictionary used:</p>	<p>0 / 8 (0.00%)</p> <p>0</p>		

MedDRA 21.1			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
hypoaesthesia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Eye disorders			
cataract			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
gastroesophageal reflux disease			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
androgenetic alopecia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
dermatitis atopic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
pain of skin			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
pruritus			

alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Musculoskeletal and connective tissue disorders synovial cyst alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Infections and infestations cellulitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) folliculitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) nasopharyngitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) paronychia alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) postoperative wound infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all) upper respiratory tract infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 1 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0		
Metabolism and nutrition disorders			

hypokalaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		

Notes:

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

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The study was terminated for lack of efficacy after an interim analysis was performed.
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Notes: