Clinical trial results:
A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study of LY2951742 with a Long-Term Open-Label Extension in Patients with Chronic Cluster Headache

Summary

EudraCT number	2014-005429-11
Trial protocol	GB DE ES DK FI BE FR NL GR IT
Global end of trial date	14 August 2019

Results information

Result version number	v1 (current)
This version publication date	30 August 2020
First version publication date	30 August 2020

Trial information

Trial identification

Sponsor protocol code	I5Q-MC-CGAM

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02438826
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 15781

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	14 August 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 August 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of this study is to evaluate the efficacy of the study drug known as galcanezumab in participants with chronic cluster headache.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 June 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Greece: 1
Country: Number of subjects enrolled	Canada: 8
Country: Number of subjects enrolled	Netherlands: 10
Country: Number of subjects enrolled	Belgium: 32
Country: Number of subjects enrolled	United States: 33
Country: Number of subjects enrolled	Finland: 4
Country: Number of subjects enrolled	Denmark: 9
Country: Number of subjects enrolled	Italy: 31
Country: Number of subjects enrolled	United Kingdom: 16
Country: Number of subjects enrolled	France: 40
Country: Number of subjects enrolled	Germany: 42
Country: Number of subjects enrolled	Spain: 11
Worldwide total number of subjects	237
EEA total number of subjects	196

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)	236
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

Study consists of a 12-week double-blind treatment phase; an optional 1-year open-label treatment phase; and a 16-week post-treatment phase (washout).

Period 1

Period 1 title	Double-Blind Treatment (DBT) Phase
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

Arm description:

Participants received placebo once a month by subcutaneous (SC) injection for 3 months.

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

Dosage and administration details:

3 subcutaneous injections of placebo administered once a month for 3 months.

Arm title	Galcanezumab 300 mg

Arm description:

Participants received galcanezumab 300 mg once a month by subcutaneous (SC) injection for 3 months.

Arm type	Experimental
Investigational medicinal product name	Galcanezumab 300 mg
Investigational medicinal product code	
Other name	LY2951742
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg of galcanezumab administered as subcutaneous injection for 3 months.

Number of subjects in period 1	Placebo	Galcanezumab 300 mg
Started	123	117
Received at Least 1 Dose of Study Drug	120	117
Completed	117	113
Not completed	6	4
Consent withdrawn by subject	1	1
Screen Failure	2	-
Adverse event, non-fatal	1	1
Protocol deviation	1	2
Lack of efficacy	1	-

Period 2

Period 2 title	Received at least 1 dose (DBT) - Period1
Is this the baseline period?	Yes[1]
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	No
Arm title	Placebo

Arm description:

Participants received placebo once a month by subcutaneous (SC) injection for 3 months.

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

Dosage and administration details:

3 subcutaneous injections of placebo administered once a month for 3 months.

Arm title	Galcanezumab 300 mg

Arm description:

Participants received galcanezumab 300 mg once a month by subcutaneous (SC) injection for 3 months.

Arm type	Experimental
Investigational medicinal product name	Galcanezumab 300 mg
Investigational medicinal product code	
Other name	LY2951742
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg of galcanezumab administered as subcutaneous injection for 3 months.

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Participants must have completed the double-blind phase to enter the optional open-label phase. One placebo treated participant chose not to enter the open-label phase.

Number of subjects in period 2	Placebo	Galcanezumab 300 mg
Started	120	117
Completed	117	113
Not completed	3	4
Consent withdrawn by subject	1	1
Adverse event, non-fatal	1	1
Lack of efficacy	1	-
Protocol deviation	-	2

Period 3

Period 3 title	Open-Label Treatment Phase-Period 2
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo/GMB 300 mg

Arm description:

Participants from placebo group received 300 mg of galcanezumab (GMB) by subcutaneous injection every 30 days, for up to a total of 12 administrations.

Arm type	Experimental
Investigational medicinal product name	Galcanezumab 300 mg
Investigational medicinal product code	
Other name	LY2951742
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg of galcanezumab administered as subcutaneous injections every 30 days, for up to a total of 12 administrations.

Arm title	GMB 300 mg/GMB 300 mg

Arm description:

Participants from galcanezumab group received 300 mg of galcanezumab by subcutaneous injection every 30 days, for up to a total of 12 administrations.

Arm type	Experimental
Investigational medicinal product name	Galcanezumab 300 mg
Investigational medicinal product code	
Other name	LY2951742
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg of galcanezumab administered as subcutaneous injections every 30 days, for up to a total of 12

administrations.

Number of subjects in period 3	Placebo/GMB 300 mg	GMB 300 mg/GMB 300 mg
Started	116	113
Completed	72	80
Not completed	44	33
Consent withdrawn by subject	6	7
Adverse event, non-fatal	11	6
Lost to follow-up	-	2
Lack of efficacy	27	18

Period 4	
Period 4 title	Post-Treatment Phase-Period 3
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	No
Arm title	Placebo/GMB 300 mg (Open-Label Treatment Phase)

Arm description:

Participants from Open-Label Treatment Phase entered this phase, they have not received any intervention during this post-treatment period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	GMB 300 mg/GMB 300 mg (Open-Label Treatment Phase)

Arm description:

Participants from Open-Label Treatment Phase entered this phase, they have not received any intervention during this post-treatment period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Placebo (Double-Blind Treatment Phase)

Arm description:

Participants from double blind treatment group entered this phase, they have not received any intervention during this post-treatment period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Galcanezumab 300 mg (Double-Blind Treatment Phase)

Arm description:

Participants from double blind treatment group entered this phase, they have not received any intervention during this post-treatment period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 4	Placebo/GMB 300 mg (Open-Label Treatment Phase)	GMB 300 mg/GMB 300 mg (Open-Label Treatment Phase)	Placebo (Double-Blind Treatment Phase)
Started	93	93	2
Completed	84	92	2
Not completed	9	1	0
Physician decision	1	-	-
Consent withdrawn by subject	1	1	-
Adverse event, non-fatal	3	-	-
Lack of efficacy	4	-	-

Number of subjects in period 4	Galcanezumab 300 mg (Double-Blind Treatment Phase)
Started	4
Completed	4
Not completed	0
Physician decision	-
Consent withdrawn by subject	-
Adverse event, non-fatal	-
Lack of efficacy	-

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo once a month by subcutaneous (SC) injection for 3 months.	
Reporting group title	Galcanezumab 300 mg
Reporting group description:	
Participants received galcanezumab 300 mg once a month by subcutaneous (SC) injection for 3 months.	

Reporting group values	Placebo	Galcanezumab 300 mg	Total
Number of subjects	120	117	237
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: years			
arithmetic mean	44.38	45.62	
standard deviation	± 10.81	± 11.03	-
Gender categorical Units: Subjects			
Female	34	31	65
Male	86	86	172
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	15	18	33
Not Hispanic or Latino	87	81	168
Unknown or Not Reported	18	18	36
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	1	2
White	101	99	200
More than one race	18	17	35
Unknown or Not Reported	0	0	0
Region of Enrollment			

Units: Subjects			
Greece	0	1	1
Canada	4	4	8
Netherlands	5	5	10
Belgium	16	16	32
United States	15	18	33
Finland	2	2	4
Denmark	5	4	9
Italy	17	14	31
United Kingdom	8	8	16
France	20	20	40
Germany	22	20	42
Spain	6	5	11
Weekly Cluster Headache Attacks			
Units: cluster headache attacks per week			
arithmetic mean	18.47	19.18	
standard deviation	± 10.66	± 9.82	-

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received placebo once a month by subcutaneous (SC) injection for 3 months.	
Reporting group title	Galcanezumab 300 mg
Reporting group description:	
Participants received galcanezumab 300 mg once a month by subcutaneous (SC) injection for 3 months.	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo once a month by subcutaneous (SC) injection for 3 months.	
Reporting group title	Galcanezumab 300 mg
Reporting group description:	
Participants received galcanezumab 300 mg once a month by subcutaneous (SC) injection for 3 months.	
Reporting group title	Placebo/GMB 300 mg
Reporting group description:	
Participants from placebo group received 300 mg of galcanezumab (GMB) by subcutaneous injection every 30 days, for up to a total of 12 administrations.	
Reporting group title	GMB 300 mg/GMB 300 mg
Reporting group description:	
Participants from galcanezumab group received 300 mg of galcanezumab by subcutaneous injection every 30 days, for up to a total of 12 administrations.	
Reporting group title	Placebo/GMB 300 mg (Open-Label Treatment Phase)
Reporting group description:	
Participants from Open-Label Treatment Phase entered this phase, they have not received any intervention during this post-treatment period.	
Reporting group title	GMB 300 mg/GMB 300 mg (Open-Label Treatment Phase)
Reporting group description:	
Participants from Open-Label Treatment Phase entered this phase, they have not received any intervention during this post-treatment period.	
Reporting group title	Placebo (Double-Blind Treatment Phase)
Reporting group description:	
Participants from double blind treatment group entered this phase, they have not received any intervention during this post-treatment period.	
Reporting group title	Galcanezumab 300 mg (Double-Blind Treatment Phase)
Reporting group description:	
Participants from double blind treatment group entered this phase, they have not received any intervention during this post-treatment period.	

Primary: Overall Mean Change from Baseline in Weekly Cluster Headache Attack Frequency

End point title	Overall Mean Change from Baseline in Weekly Cluster Headache Attack Frequency

End point description:

Number of cluster headache attacks was recorded daily by study participants in their ePRO Diary, Baseline and 12 weeks of daily data during double-blind treatment phase will be converted into 14-calendar day intervals: the baseline 14-day interval, Weeks 1/2, 3/4, 5/6, 7/8, 9/10, and 11/12. Next, the biweekly interval results were adjusted to 7-day (weekly) interval in order to report the outcome as weekly frequency. Overall mean change from baseline is derived from mixed model repeated measures (MMRM) analysis. Least Square (LS) means were calculated using MMRM model with treatment, sex, verapamil use, pooled investigative site, week, baseline, and treatment by week as fixed effects. Analysis Population Description: All randomized participants who received at least 1 dose of study drug,

and had baseline and at least one post baseline value.

End point type	Primary

End point timeframe:

Baseline, Week 1 through Week 12

End point values	Placebo	Galcanezumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	120	117		
Units: cluster headache attacks per week				
least squares mean (standard error)	-4.59 (± 0.79)	-5.38 (± 0.81)		

Statistical analyses

Statistical analysis title	Cluster Headache Attack Frequency
Comparison groups	Placebo v Galcanezumab 300 mg
Number of subjects included in analysis	237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.334 [1]
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.77
upper limit	1.17

Notes:

[1] - Cui, Hung, Wang (CHW) procedure applied

Secondary: Percentage of Participants with a 50% or Greater Reduction from Baseline in the Weekly Number of Cluster Headache Attacks

End point title	Percentage of Participants with a 50% or Greater Reduction from Baseline in the Weekly Number of Cluster Headache Attacks

End point description:

A 50% responder is any participant who has a ≥50% reduction from baseline in the weekly number of cluster headache attacks in a 14-day interval: Weeks 1/2, Weeks 3/4, Weeks 5/6, Weeks 7/8, Weeks 9/10, and Weeks 11/12. Mean percentage of participants is derived from the average of weeks 1/2 to weeks 11/12 from generalized linear mixed model repeated measures method with treatment, sex, verapamil use, week, treatment by week, and baseline as fixed effects.

APD: All randomized participants who received at least 1 dose of study drug, and had baseline and at least 1 post baseline value.

End point type	Secondary

End point timeframe:

Baseline, Week 1 through Week 12

End point values	Placebo	Galcanezumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	120	117		
Units: percentage of participants				
arithmetic mean (standard error)	27.1 (± 3.5)	32.6 (± 3.8)		

Statistical analyses

Statistical analysis title	50% Greater Reduction in Cluster Headache Attacks
Comparison groups	Placebo v Galcanezumab 300 mg
Number of subjects included in analysis	237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.17 [2]
Method	Mixed models analysis
Parameter estimate	Odds ratio (OR)
Point estimate	1.297
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	2.028

Notes:

[2] - Cui, Hung, Wang (CHW) procedure applied

Secondary: Percentage of Participants With a Sustained Response of 50% or Greater Reduction From Baseline in the Weekly Number of Cluster Headache Attacks

End point title	Percentage of Participants With a Sustained Response of 50% or Greater Reduction From Baseline in the Weekly Number of Cluster Headache Attacks

End point description:

Sustained Response is defined as a 50% or greater reduction in the weekly cluster attack frequency from baseline to Weeks 3/4 and maintained at Weeks 5/6, Weeks 7/8, Weeks 9/10, and Weeks 11/12. Percentage of participants with a sustained response was analyzed using Koch's nonparametric randomization-based analysis of covariance method. This method adjusted for pooled investigative site by including it as a stratification variable. It also adjusted for sex, verapamil use and baseline value. APD: All randomized participants who received at least 1 dose of study drug, had a baseline, and at least one post baseline value.

End point type	Secondary

End point timeframe:

Baseline, Week 3 through Week 12

End point values	Placebo	Galcanezumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	120	117		
Units: percentage of participants				
number (not applicable)	17.50	16.24		

Statistical analyses

Statistical analysis title	Sustained Response of Cluster Headache Attacks
Comparison groups	Placebo v Galcanezumab 300 mg
Number of subjects included in analysis	237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.946 [3]
Method	Mixed models analysis

Notes:

[3] - Chui, Hung, Wang (CHW) procedure applied)

Secondary: Percentage of Participants with a 30% Reduction in the Weekly Number of Cluster Headache Attacks

End point title	Percentage of Participants with a 30% Reduction in the Weekly Number of Cluster Headache Attacks

End point description:

A 30% responder is any participant who has a ≥30% reduction from baseline in the weekly number of cluster headache attacks in a 14-day interval. Weeks 1/2, 3/4, 5/6, 7/8, 9/10, and 11/12. Mean percentage of participants is derived from the average of weeks 1/2 to weeks 11/12 from generalized linear mixed model repeated measures method with treatment, sex, verapamil use, week, treatment by week, and baseline as fixed effects.

APD: All randomized participants who received at least 1 dose of study drug, and had baseline and at least 1 post baseline value.

End point type	Secondary

End point timeframe:

Baseline, Week 1 through Week 12

End point values	Placebo	Galcanezumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	120	117		
Units: percentage of participants				
arithmetic mean (standard error)	39.0 (± 3.9)	49.1 (± 4.1)		

Statistical analyses

Statistical analysis title	30% Reduction in Weekly Cluster Headache Attacks
Comparison groups	Placebo v Galcanezumab 300 mg
Number of subjects included in analysis	237
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.057
Method	Mixed models analysis
Parameter estimate	Odds ratio (OR)
Point estimate	1.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.987
upper limit	2.309

Secondary: Percentage of Participants Reporting a Score of 1 or 2 on the Patient Global Impression of Improvement (PGI-I)

End point title	Percentage of Participants Reporting a Score of 1 or 2 on the Patient Global Impression of Improvement (PGI-I)

End point description:

PGI-I requests participants to mark the box that best describes their cluster headache condition since they started taking the medicine. The options in the displayed boxes are represented on a 7-point scale, with 1 = very much better, 2 = much better, 3 = a little better, 4 = no change, 5 = a little worse, 6 = much worse, and 7 = very much worse. Percentage of participants were derived with a generalized linear mixed model repeated measures method with treatment, sex, verapamil use, baseline cluster headache attack category, month, and treatment by month as fixed effects.

APD: All randomized participants who received at least one dose of study drug and had PGI-I measurement at Week 4.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	Galcanezumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	88		
Units: percentage of participants				
number (not applicable)	19.4	21.5		

Statistical analyses

Statistical analysis title	Patient Global Impression of Improvement (PGI-I)
Comparison groups	Placebo v Galcanezumab 300 mg
Number of subjects included in analysis	180
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.713
Method	Mixed models analysis
Parameter estimate	Odds ratio (OR)
Point estimate	1.141
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.563
upper limit	2.314

Secondary: Percentage of Participants Reporting a Score of 1 or 2 on the Patient Global Impression of Improvement (PGI-I)

End point title	Percentage of Participants Reporting a Score of 1 or 2 on the Patient Global Impression of Improvement (PGI-I)

End point description:

PGI-I requests participants to mark the box that best describes their cluster headache condition since they started taking the medicine. The options in the displayed boxes are represented on a 7-point scale, with 1 = very much better, 2 = much better, 3 = a little better, 4 = no change, 5 = a little worse, 6 = much worse, and 7 = very much worse. Percentage of participants were derived with a generalized linear mixed model repeated measures method with treatment, sex, verapamil use, baseline cluster headache attack category, month, and treatment by month as fixed effects.

APD: All randomized participants who received at least one dose of study drug and had PGI-I measurement at Week 8.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	Galcanezumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	86		
Units: percentage of participants				
number (not applicable)	32.0	32.1		

Statistical analyses

Statistical analysis title	Patient Global Impression of Improvement (PGI-I)
Comparison groups	Placebo v Galcanezumab 300 mg
Number of subjects included in analysis	183
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.979
Method	Mixed models analysis
Parameter estimate	Odds ratio (OR)
Point estimate	1.008
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.548
upper limit	1.856

Secondary: Percentage of Participants Reporting a Score of 1 or 2 on the Patient Global Impression of Improvement (PGI-I)

End point title	Percentage of Participants Reporting a Score of 1 or 2 on the Patient Global Impression of Improvement (PGI-I)

End point description:

PGI-I requests participants to mark the box that best describes their cluster headache condition since they started taking the medicine. The options in the displayed boxes are represented on a 7-point scale, with 1 = very much better, 2 = much better, 3 = a little better, 4 = no change, 5 = a little worse, 6 = much worse, and 7 = very much worse. Percentage of participants were derived with a generalized linear mixed model repeated measures method with treatment, sex, verapamil use, baseline cluster headache attack category, month, and treatment by month as fixed effects.

APD: All randomized participants who received at least one dose of study drug and had PGI-I measurement at week 12.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	Galcanezumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	95	95		
Units: percentage of participants				
number (not applicable)	35.6	30.4		

Statistical analyses

Statistical analysis title	Patient Global Impression of Improvement (PGI-I)
Comparison groups	Placebo v Galcanezumab 300 mg
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.437
Method	Mixed models analysis
Parameter estimate	Odds ratio (OR)
Point estimate	0.788
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.431
upper limit	1.44

Secondary: Percentage of Participants With Suicidal Ideation Assessed by Columbia - Suicide Severity Rating Scale (C-SSRS)

End point title	Percentage of Participants With Suicidal Ideation Assessed by Columbia - Suicide Severity Rating Scale (C-SSRS)

End point description:

C-SSRS captures the occurrence, severity, and frequency of suicide-related thoughts and behaviors during the assessment period. The scale includes suggested questions to solicit the type of information needed to determine if a suicide-related thought or behavior occurred. Some questions are binary responses (yes/no) and some are on a scale of 1 (low severity) to 5 (high severity). Suicidal ideation: a "yes" answer to any of 5 suicidal ideation questions: wish to be dead, non-specific active suicidal thoughts, active suicidal ideation with any methods without intent to act, active suicidal ideation with some intent to act without specific plan, active suicidal ideation with specific plan and intent.

APD: All randomized participants who received at least one dose of study drug and had at least one post baseline C-SSRS assessment.

End point type	Secondary

End point timeframe:

Week 1 through Week 12

End point values	Placebo	Galcanezumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	116		
Units: percentage of participants				
number (not applicable)	5.04	4.31		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Suicidal Behaviors Assessed by Columbia - Suicide Severity Rating Scale (C-SSRS)

End point title	Percentage of Participants With Suicidal Behaviors Assessed by Columbia - Suicide Severity Rating Scale (C-SSRS)

End point description:

C-SSRS captures the occurrence, severity, and frequency of suicide-related thoughts and behaviors during the assessment period. The scale includes suggested questions to solicit the type of information needed to determine if a suicide-related thought or behavior occurred. Some questions are binary responses (yes/no) and some are on a scale of 1 (low severity) to 5 (high severity). Suicidal behavior: a "yes" answer to any of 5 suicidal behavior questions: preparatory acts or behavior, aborted attempt, interrupted attempt, actual attempt, and completed suicide.

APD: All randomized participants who received at least one dose of study drug and had at least one post baseline C-SSRS assessment.

End point type	Secondary

End point timeframe:

Week 1 through Week 12

End point values	Placebo	Galcanezumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	116		
Units: percentage of participants				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Developing Anti-Drug Antibodies (ADA) to Galcanezumab (LY2951742)

End point title	Percentage of Participants Developing Anti-Drug Antibodies (ADA) to Galcanezumab (LY2951742)

End point description:

Treatment emergent (TE) ADA evaluable participant is considered to be TE ADA+ if the subject has at least one post-baseline titer that is a 4-fold or greater increase in titer from baseline measurement. If baseline result is ADA Not Present, then the participant is TE ADA+ if there is at least one post-baseline result of ADA present with titer >= 1: 20.

APD: All randomized participants who received at least one dose of study drug and had non-missing baseline ADA result, and at least one non-missing post baseline ADA result.

End point type	Secondary

End point timeframe:

Baseline, Week 1 through Week 12

End point values	Placebo	Galcanezumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	115	113		
Units: percentage of participants				
number (not applicable)	0	0.88		

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Serum Concentration of Galcanezumab

End point title	Pharmacokinetics (PK): Serum Concentration of Galcanezumab

End point description:

Pharmacokinetics (PK): Serum Concentration of Galcanezumab

APD: All randomized participants who received at least 1 dose of study drug and had evaluable galcanezumab PK samples at Week 2.

End point type	Secondary

End point timeframe:

Week 2

End point values	Galcanezumab 300 mg			
Subject group type	Reporting group			
Number of subjects analysed	90			
Units: nanogram per milliliter				
arithmetic mean (standard deviation)	30600 (± 10700)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Serum Concentration of Galcanezumab

End point title	Pharmacokinetics (PK): Serum Concentration of Galcanezumab

End point description:

Pharmacokinetics (PK): Serum Concentration of Galcanezumab

APD: All randomized participants who received at least 1 dose of study drug and had evaluable galcanezumab PK samples at Week 4.

End point type	Secondary

End point timeframe:

Week 4

End point values	Galcanezumab 300 mg			
Subject group type	Reporting group			
Number of subjects analysed	96			
Units: nanogram per milliliter				
arithmetic mean (standard deviation)	20200 (± 6780)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Serum Concentration of Galcanezumab

End point title	Pharmacokinetics (PK): Serum Concentration of Galcanezumab

End point description:

Pharmacokinetics (PK): Serum Concentration of Galcanezumab

APD: All randomized participants who received at least 1 dose of study drug and had evaluable galcanezumab PK samples at Week 8.

End point type	Secondary

End point timeframe:

Week 8

End point values	Galcanezumab 300 mg			
Subject group type	Reporting group			
Number of subjects analysed	94			
Units: nanogram per milliliter				
arithmetic mean (standard deviation)	29700 (± 11500)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Serum Concentration of Galcanezumab

End point title	Pharmacokinetics (PK): Serum Concentration of Galcanezumab

End point description:

Pharmacokinetics (PK): Serum Concentration of Galcanezumab

APD: All randomized participants who received at least 1 dose of study drug and had evaluable galcanezumab PK samples at Week 12.

End point type	Secondary

End point timeframe:

Week 12

End point values	Galcanezumab 300 mg			
Subject group type	Reporting group			
Number of subjects analysed	96			
Units: nanogram per milliliter				
arithmetic mean (standard deviation)	31100 (± 11900)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 1 Year 7 Months

Adverse event reporting additional description:

All randomized participants who received at least 1 dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Placebo - Double-Blind Treatment Phase

Reporting group description:

Participants received placebo once a month by subcutaneous (SC) injection for 3 months.

Reporting group title	Galcanezumab 300mg - Double-Blind Treatment Phase

Reporting group description:

Participants received galcanezumab 300 mg once a month by subcutaneous (SC) injection for 3 months.

Reporting group title	Placebo/Galcanezumab 300mg - Open-Label Treatment Phase

Reporting group description:

Participants from placebo group received galcanezumab (GMB) as three 100 mg subcutaneous injections every 30 days, for up to a total of 12 administrations.

Reporting group title	Galcanezumab 300mg/Galcanezumab 300mg - Open-Label Treatment

Reporting group description:

Participants from galcanezumab group received galcanezumab as three 100 mg subcutaneous injections every 30 days, for up to a total of 12 administrations.

Reporting group title	Placebo - Follow-up Phase

Reporting group description:

Participants from double blind treatment group entered this phase, they have not received any intervention during this post-treatment period.

Reporting group title	Galcanezumab 300mg - Follow-up Phase

Reporting group description:

Participants from double blind treatment group entered this phase, they have not received any intervention during this post-treatment period.

Reporting group title	Placebo/Galcanezumab 300mg - Follow-up Phase

Reporting group description:

Participants from Open-Label Treatment Phase entered this phase, they have not received any intervention during this post-treatment period.

Reporting group title	Galcanezumab 300mg/Galcanezumab 300mg - Follow-up Phase

Reporting group description:

Participants from Open-Label Treatment Phase entered this phase, they have not received any intervention during this post-treatment period.

Serious adverse events	Placebo - Double-Blind Treatment Phase	Galcanezumab 300mg - Double-Blind Treatment Phase	Placebo/Galcanezumab 300mg - Open-Label Treatment Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 120 (2.50%)	2 / 117 (1.71%)	11 / 116 (9.48%)

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)			
breast cancer stage iii			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
colon neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pituitary tumour			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
arthrodesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injection site urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
pregnancy of partner			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
extradural haematoma			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
kidney rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
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			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	1 / 117 (0.85%)	0 / 116 (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
palpitations			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cluster headache			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
reversible cerebral vasoconstriction syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
amaurosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
constipation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	1 / 117 (0.85%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
melaena			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ureterolithiasis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
rhabdomyolysis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
helicobacter gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal abscess			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
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	Galcanezumab 300mg/Galcanezumab 300mg - Open-Label Treatment	Placebo - Follow-up Phase	Galcanezumab 300mg - Follow-up Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 113 (8.85%)	0 / 2 (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)			
breast cancer stage iii			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
colon neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
pituitary tumour			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
Surgical and medical procedures			
arthrodesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
injection site urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
Social circumstances			
pregnancy of partner			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
Injury, poisoning and procedural complications			
extradural haematoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
kidney rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
road traffic accident			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
palpitations			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
cluster headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 113 (1.77%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
reversible cerebral vasoconstriction syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
amaurosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
constipation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
melaena			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
small intestinal obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
Renal and urinary disorders			
ureterolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
Musculoskeletal and connective tissue disorders			
rhabdomyolysis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
gastroenteritis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
helicobacter gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (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
rectal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo/Galcanezumab 300mg - Follow-up Phase	Galcanezumab 300mg/Galcanezumab 300mg - Follow-up Phase	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 93 (0.00%)	5 / 93 (5.38%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer stage iii			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon neoplasm			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pituitary tumour			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	1 / 93 (1.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
arthrodesis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
injection site urticaria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
pregnancy of partner			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	1 / 93 (1.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
extradural haematoma			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
kidney rupture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	1 / 93 (1.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
road traffic accident			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
palpitations			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
cerebral ischaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cluster headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
reversible cerebral vasoconstriction syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
amaurosis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
constipation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
melaena			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
small intestinal obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	1 / 93 (1.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
ureterolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	1 / 93 (1.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
rhabdomyolysis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diverticulitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
helicobacter gastritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal abscess			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract infection bacterial			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo - Double-Blind Treatment Phase	Galcanezumab 300mg - Double-Blind Treatment Phase	Placebo/Galcanezumab 300mg - Open-Label Treatment Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	60 / 120 (50.00%)	68 / 117 (58.12%)	69 / 116 (59.48%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 120 (2.50%)	2 / 117 (1.71%)	2 / 116 (1.72%)
occurrences (all)	3	2	2
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	1 / 117 (0.85%)	2 / 116 (1.72%)
occurrences (all)	1	4	2
chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 120 (1.67%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences (all)	2	0	0
fatigue			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	7 / 120 (5.83%)	5 / 117 (4.27%)	6 / 116 (5.17%)
occurrences (all)	9	5	6
influenza like illness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	5 / 117 (4.27%)	4 / 116 (3.45%)
occurrences (all)	1	8	4
injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	8 / 117 (6.84%)	5 / 116 (4.31%)
occurrences (all)	1	11	6
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	11 / 120 (9.17%)	14 / 117 (11.97%)	16 / 116 (13.79%)
occurrences (all)	15	32	32
injection site pruritus			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	7 / 117 (5.98%)	5 / 116 (4.31%)
occurrences (all)	1	10	7
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	1 / 117 (0.85%)	8 / 116 (6.90%)
occurrences (all)	0	2	20
injection site swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	1 / 117 (0.85%)	1 / 116 (0.86%)
occurrences (all)	1	1	1
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	2 / 117 (1.71%)	1 / 116 (0.86%)
occurrences (all)	0	7	1
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	3 / 117 (2.56%)	2 / 116 (1.72%)
occurrences (all)	1	3	2
Immune system disorders			
seasonal allergy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
dysmenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 34 (0.00%)	1 / 31 (3.23%)	1 / 33 (3.03%)
occurrences (all)	0	1	1
menstrual disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 34 (0.00%)	1 / 31 (3.23%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
ovarian cyst			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed[3]	0 / 34 (0.00%)	0 / 31 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
uterine haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 34 (0.00%)	0 / 31 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences (all)	1	0	1
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	5 / 116 (4.31%)
occurrences (all)	0	0	6
insomnia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 120 (3.33%)	1 / 117 (0.85%)	2 / 116 (1.72%)
occurrences (all)	4	1	4
Investigations			
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	1 / 117 (0.85%)	3 / 116 (2.59%)
occurrences (all)	1	1	3
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 120 (1.67%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences (all)	2	0	0
ligament sprain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences (all)	1	0	1
Cardiac disorders			

palpitations			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 120 (2.50%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences (all)	3	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 120 (5.00%)	5 / 117 (4.27%)	4 / 116 (3.45%)
occurrences (all)	7	5	5
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 120 (3.33%)	2 / 117 (1.71%)	2 / 116 (1.72%)
occurrences (all)	5	3	2
Ear and labyrinth disorders			
tinnitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	3 / 117 (2.56%)	1 / 116 (0.86%)
occurrences (all)	1	3	1
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 120 (2.50%)	1 / 117 (0.85%)	0 / 116 (0.00%)
occurrences (all)	4	1	0
Eye disorders			
visual impairment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 117 (0.00%)	3 / 116 (2.59%)
occurrences (all)	1	0	3
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 120 (2.50%)	2 / 117 (1.71%)	2 / 116 (1.72%)
occurrences (all)	3	2	2
constipation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 120 (1.67%)	2 / 117 (1.71%)	6 / 116 (5.17%)
occurrences (all)	2	2	8

diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 120 (5.00%)	1 / 117 (0.85%)	5 / 116 (4.31%)
occurrences (all)	6	1	6
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 120 (5.00%)	6 / 117 (5.13%)	3 / 116 (2.59%)
occurrences (all)	8	7	3
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 120 (2.50%)	3 / 117 (2.56%)	2 / 116 (1.72%)
occurrences (all)	4	3	2
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 117 (0.00%)	1 / 116 (0.86%)
occurrences (all)	1	0	1
Endocrine disorders			
thyroid mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 120 (3.33%)	0 / 117 (0.00%)	5 / 116 (4.31%)
occurrences (all)	4	0	6
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	5 / 117 (4.27%)	4 / 116 (3.45%)
occurrences (all)	1	5	4

bursitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 117 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 120 (2.50%)	3 / 117 (2.56%)	4 / 116 (3.45%)
occurrences (all)	3	3	5
neck pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 117 (0.00%)	2 / 116 (1.72%)
occurrences (all)	1	0	2
pain in extremity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	4 / 117 (3.42%)	3 / 116 (2.59%)
occurrences (all)	2	4	3
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	2 / 117 (1.71%)	4 / 116 (3.45%)
occurrences (all)	1	2	5
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 120 (0.83%)	3 / 117 (2.56%)	3 / 116 (2.59%)
occurrences (all)	1	3	3
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 120 (2.50%)	2 / 117 (1.71%)	8 / 116 (6.90%)
occurrences (all)	4	2	8
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	15 / 120 (12.50%)	12 / 117 (10.26%)	14 / 116 (12.07%)
occurrences (all)	16	13	19
sinusitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	2 / 120 (1.67%)	1 / 117 (0.85%)	3 / 116 (2.59%)
occurrences (all)	2	1	3
tracheitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	1 / 117 (0.85%)	3 / 116 (2.59%)
occurrences (all)	0	1	4
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 120 (1.67%)	1 / 117 (0.85%)	2 / 116 (1.72%)
occurrences (all)	2	1	2
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 120 (0.00%)	2 / 117 (1.71%)	1 / 116 (0.86%)
occurrences (all)	0	2	1
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 34 (0.00%)	0 / 31 (0.00%)	1 / 33 (3.03%)
occurrences (all)	0	0	1

Non-serious adverse events	Galcanezumab 300mg/Galcanezumab 300mg - Open-Label Treatment	Placebo - Follow-up Phase	Galcanezumab 300mg - Follow-up Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	72 / 113 (63.72%)	1 / 2 (50.00%)	2 / 4 (50.00%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 113 (3.54%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 113 (1.77%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
chest pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
fatigue			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
influenza like illness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 113 (3.54%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	6	0	0
injection site erythema			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 113 (1.77%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	7	0	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	8 / 113 (7.08%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	14	0	0
injection site pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 113 (1.77%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	10	0	0
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
injection site swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0

pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
Immune system disorders			
seasonal allergy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
Reproductive system and breast disorders			
dysmenorrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 29 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
menstrual disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 29 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	1 / 29 (3.45%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
uterine haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	0 / 29 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 113 (3.54%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	4	0	1
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 113 (1.77%)	1 / 2 (50.00%)	0 / 4 (0.00%)
occurrences (all)	2	1	0

insomnia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 113 (5.31%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	6	0	0
Investigations			
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
ligament sprain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Cardiac disorders			
palpitations			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 113 (1.77%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	6	0	0
Ear and labyrinth disorders			
tinnitus			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
visual impairment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 113 (3.54%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
constipation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 113 (3.54%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 113 (3.54%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 113 (1.77%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Endocrine disorders			
thyroid mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 113 (0.00%)	0 / 2 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 113 (5.31%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	6	0	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	10 / 113 (8.85%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	12	0	0
bursitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
myalgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
neck pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 113 (1.77%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
pain in extremity			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	2 / 113 (1.77%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 113 (4.42%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	5	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	17 / 113 (15.04%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	24	0	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 113 (5.31%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	6	0	0
tracheitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 113 (0.88%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 113 (4.42%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	5	0	0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	3 / 113 (2.65%)	0 / 2 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 29 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo/Galcanezumab 300mg - Follow-up Phase	Galcanezumab 300mg/Galcanezumab 300mg - Follow-up Phase	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 93 (19.35%)	16 / 93 (17.20%)	
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 93 (1.08%)	0 / 93 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 93 (2.15%)	1 / 93 (1.08%)	
occurrences (all)	2	1	
chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
fatigue			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
influenza like illness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	1 / 93 (1.08%)	
occurrences (all)	0	1	
injection site erythema			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
injection site pruritus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
injection site swelling			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
non-cardiac chest pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 93 (1.08%)	0 / 93 (0.00%)	
occurrences (all)	1	0	
pyrexia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
seasonal allergy			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
dysmenorrhoea			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed[1]	0 / 25 (0.00%)	0 / 25 (0.00%)	
occurrences (all)	0	0	
menstrual disorder			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[2]	0 / 25 (0.00%)	0 / 25 (0.00%)	
occurrences (all)	0	0	
ovarian cyst			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[3]	0 / 25 (0.00%)	0 / 25 (0.00%)	
occurrences (all)	0	0	
uterine haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[4]	1 / 25 (4.00%)	0 / 25 (0.00%)	
occurrences (all)	3	0	
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 93 (2.15%)	1 / 93 (1.08%)	
occurrences (all)	2	1	
depression			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 93 (2.15%)	0 / 93 (0.00%)	
occurrences (all)	2	0	
insomnia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 93 (1.08%)	0 / 93 (0.00%)	
occurrences (all)	1	0	
Investigations			
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 93 (2.15%)	0 / 93 (0.00%)	
occurrences (all)	2	0	
Injury, poisoning and procedural complications			

fall			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
ligament sprain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
palpitations			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 93 (1.08%)	0 / 93 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 93 (1.08%)	0 / 93 (0.00%)	
occurrences (all)	1	0	
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 93 (2.15%)	0 / 93 (0.00%)	
occurrences (all)	2	0	
Ear and labyrinth disorders			
tinnitus			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
vertigo			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
visual impairment			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	

Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
constipation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 93 (1.08%)	2 / 93 (2.15%)	
occurrences (all)	1	2	
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	2 / 93 (2.15%)	
occurrences (all)	0	2	
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 93 (1.08%)	0 / 93 (0.00%)	
occurrences (all)	4	0	
vomiting			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	1 / 93 (1.08%)	
occurrences (all)	0	1	
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
nephrolithiasis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
thyroid mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue			

disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 93 (1.08%)	1 / 93 (1.08%)	
occurrences (all)	1	1	
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	2 / 93 (2.15%)	
occurrences (all)	0	2	
bursitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
myalgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
neck pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 93 (2.15%)	2 / 93 (2.15%)	
occurrences (all)	2	2	
pain in extremity			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	1 / 93 (1.08%)	
occurrences (all)	0	1	
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 93 (1.08%)	1 / 93 (1.08%)	
occurrences (all)	1	1	
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 93 (2.15%)	1 / 93 (1.08%)	
occurrences (all)	2	1	
influenza			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 93 (4.30%)	0 / 93 (0.00%)	
occurrences (all)	4	0	
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 93 (3.23%)	2 / 93 (2.15%)	
occurrences (all)	3	2	
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
tracheitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 93 (0.00%)	0 / 93 (0.00%)	
occurrences (all)	0	0	
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[5]	0 / 25 (0.00%)	0 / 25 (0.00%)	
occurrences (all)	0	0	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.
[3] - 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: Gender specific events occurring only in male or female participants have had the number

of participants at risk adjusted accordingly.

[4] - 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: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

[5] - 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: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 March 2015	Protocol (a) 1) Updated planned duration of treatment. 2) Updated primary endpoint duration. 3) Updated Inclusion and Exclusion Criteria.
22 December 2015	Protocol (b) -Added rescreening details (Inclusion Criteria 3).
10 February 2017	Protocol (c) -Updated rescreening details (Inclusion Criterion 3b and Exclusion Criterion 24d).
28 March 2018	Protocol (d): 1) Duration of primary analysis was changed from Week 3/4 to 12-Week. 2) Updated blinding information.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported