Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled Study of Galcanezumab in Adults with Treatment-Resistant Migraine - The CONQUER Study

Summary

EudraCT number	2018-000600-42
Trial protocol	FR DE ES CZ BE NL HU DK GB
Global end of trial date	19 September 2019

Results information

Result version number	v1 (current)
This version publication date	05 July 2020
First version publication date	05 July 2020

Trial information

Trial identification

Sponsor protocol code	I5Q-MC-CGAW

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03559257
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16670

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	19 September 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 September 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to assess the safety and efficacy of galcanezumab in people with treatment-resistant episodic or chronic migraine.

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	31 July 2018
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	Spain: 56
Country: Number of subjects enrolled	United Kingdom: 7
Country: Number of subjects enrolled	United States: 90
Country: Number of subjects enrolled	Belgium: 27
Country: Number of subjects enrolled	Canada: 11
Country: Number of subjects enrolled	Czech Republic: 109
Country: Number of subjects enrolled	France: 30
Country: Number of subjects enrolled	Germany: 26
Country: Number of subjects enrolled	Hungary: 16
Country: Number of subjects enrolled	Japan: 42
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 28
Country: Number of subjects enrolled	Netherlands: 20
Worldwide total number of subjects	462
EEA total number of subjects	291

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)	433
From 65 to 84 years	29
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Total 463 participants were randomized and 462 participants received at least one dose of study drug. one participant was screen failure.

Pre-assignment

Screening details:

NA

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received matching placebo every month for three months by subcutaneous (SC) injection.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received matching placebo every month for three months by SC injection.

Arm title	Galcanezumab 120mg

Arm description:

Participants received initial loading dose of 240 milligrams (mg) of galcanezumab followed by 120mg galcanezumab every month for two months by SC injection.

Arm type	Experimental
Investigational medicinal product name	Galcanezumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received initial loading dose of 240 milligrams (mg) of Galcanezumab followed by 120mg Galcanezumab every month for two months by SC injection.

Number of subjects in period 1	Placebo	Galcanezumab 120mg
Started	230	232
Completed	226	225
Not completed	4	7
Consent withdrawn by subject	2	1
Adverse event, non-fatal	-	1
Lack of efficacy	1	1
Protocol deviation	1	4

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Galcanezumab 120mg

Arm description:

Participants received initial loading dose of 240mg galcanezumab followed by 120mg every month for two months during open label treatment phase.

Arm type	Experimental
Investigational medicinal product name	Galcanezumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received initial loading dose of 240mg Galcanezumab followed by 120mg every month for two months during open label treatment phase by subcutaneous injection.

Arm title	Galcanezumab 120mg

Arm description:

Participants received 120mg of galcanezumab every month for three months by subcutaneous injection.

Arm type	Experimental
Investigational medicinal product name	Galcanezumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 120mg of Galcanezumab every month for three months during open label treatment period by subcutaneous injection.

Number of subjects in period 2[1]	Galcanezumab 120mg	Galcanezumab 120mg
Started	225	224
Completed	215	217
Not completed	10	7
Consent withdrawn by subject	3	-
Physician decision	-	1
Adverse event, non-fatal	1	4
Lost to follow-up	1	-
Lack of efficacy	3	2
Protocol deviation	2	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: One participant in placebo group who completed double blind period has withdrawn from the study.
One participant in Galcanezumab group who completed double blind period had discontinued due to AE.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received matching placebo every month for three months by subcutaneous (SC) injection.	
Reporting group title	Galcanezumab 120mg
Reporting group description:	
Participants received initial loading dose of 240 milligrams (mg) of galcanezumab followed by 120mg galcanezumab every month for two months by SC injection.	

Reporting group values	Placebo	Galcanezumab 120mg	Total
Number of subjects	230	232	462
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	45.67	45.87	
standard deviation	± 12.33	± 11.34	-
Gender categorical Units: Subjects			
Female	202	195	397
Male	28	37	65
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	16	15	31
Not Hispanic or Latino	174	172	346
Unknown or Not Reported	40	45	85
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	0	1
Asian	35	37	72
Native Hawaiian or Other Pacific Islander	0	1	1
Black or African American	2	3	5
White	182	183	365
More than one race	3	0	3
Unknown or Not Reported	7	8	15

Monthly Migraine Headache Days Units: Days			
arithmetic mean	13.01	13.44	
standard deviation	± 5.73	± 6.08	-

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received matching placebo every month for three months by subcutaneous (SC) injection.	
Reporting group title	Galcanezumab 120mg
Reporting group description:	
Participants received initial loading dose of 240 milligrams (mg) of galcanezumab followed by 120mg galcanezumab every month for two months by SC injection.	
Reporting group title	Galcanezumab 120mg
Reporting group description:	
Participants received initial loading dose of 240mg galcanezumab followed by 120mg every month for two months during open label treatment phase.	
Reporting group title	Galcanezumab 120mg
Reporting group description:	
Participants received 120mg of galcanezumab every month for three months by subcutaneous injection.	

Primary: Overall Mean Change from Baseline in the Number of Monthly Migraine Headache Days

End point title	Overall Mean Change from Baseline in the Number of Monthly Migraine Headache Days
End point description:	
Migraine Headache Day (MHD): A calendar day on which a migraine headache or probable migraine headache occurred. Overall mean is derived from the average of months 1 to 3 from mixed model repeated measures (MMRM) model. Least square (LS) Mean was calculated using MMRM model with treatment, pooled country, month, treatment by month, baseline, and baseline by month as fixed effects. All randomized participants who received at least one dose of study drug and had baseline and at least one post baseline value.	
End point type	Primary
End point timeframe:	
Baseline, Month 1 through Month 3	

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	228	230		
Units: Days				
least squares mean (standard error)	-1.02 (± 0.32)	-4.14 (± 0.32)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Galcanezumab 120mg v Placebo

Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-3.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.92
upper limit	-2.32
Variability estimate	Standard error of the mean
Dispersion value	0.41

Secondary: Overall Mean Change from Baseline in the Number of Monthly Migraine Headache Days in Participants with Episodic Migraine

End point title	Overall Mean Change from Baseline in the Number of Monthly Migraine Headache Days in Participants with Episodic Migraine

End point description:

MHD: A calendar day on which a migraine headache or probable migraine headache occurred.
Overall mean is derived from the average of months 1 to 3 from MMRM model. Least square (LS) Mean was calculated using MMRM model with treatment, pooled country, month, treatment by month, baseline, and baseline by month as fixed effects.

APD: All randomized episodic migraine participants who received at least one dose of study drug and had baseline and at least one post baseline value.

End point type	Secondary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	137		
Units: Days				
least squares mean (standard error)	-0.31 (± 0.34)	-2.88 (± 0.34)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg

Number of subjects included in analysis	269
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-2.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.41
upper limit	-1.72
Variability estimate	Standard error of the mean
Dispersion value	0.43

Secondary: Percentage of Participants with ≥50% Reduction from Baseline in Monthly Migraine Headache Days

End point title	Percentage of Participants with ≥50% Reduction from Baseline in Monthly Migraine Headache Days

End point description:

MHD: A calendar day on which a migraine headache or probable migraine headache occurred.

Overall mean percentage across months 1 through 3 of patients with at least a 50% reduction in monthly MHDs from baseline using a categorical pseudo likelihood-based repeated measures model for binary responder indicator with fixed, categorical effects of treatment, month, treatment by month, and continuous, fixed covariate of baseline monthly MHD.

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

End point type	Secondary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	228	230		
Units: Percentage of Participants				
number (confidence interval 95%)	13.3 (10.2 to 17.3)	37.7 (32.9 to 42.8)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg

Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Odds ratio (OR)
Point estimate	3.935
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.719
upper limit	5.693

Secondary: Percentage of Participants With Episodic Migraine With ≥50% Reduction From Baseline in Monthly Migraine Headache Days

End point title	Percentage of Participants With Episodic Migraine With ≥50% Reduction From Baseline in Monthly Migraine Headache Days

End point description:

MHD: A calendar day on which a migraine headache or probable migraine headache occurred.

Overall mean percentage across months 1 through 3 of patients with at least a 50% reduction in monthly MHDs from baseline using a categorical pseudo likelihood-based repeated measures model for binary responder indicator with fixed, categorical effects of treatment, month, treatment by month, and continuous, fixed covariate of baseline monthly MHD.

APD: All randomized episodic migraine participants who received at least one dose of study drug and had baseline and at least one post baseline value.

End point type	Secondary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	137		
Units: Percentage of Participants				
number (confidence interval 95%)	17.1 (12.7 to 22.7)	41.8 (35.7 to 48.1)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg

Number of subjects included in analysis	269
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Pseudo likelihood-based repeated measure
Parameter estimate	Odds ratio (OR)
Point estimate	3.481
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.252
upper limit	5.381

Secondary: Mean Change from Baseline in the Role Function-Restrictive Domain Score of the Migraine-Specific Quality of Life Questionnaire Version 2.1 (MSQ v2.1)

End point title	Mean Change from Baseline in the Role Function-Restrictive Domain Score of the Migraine-Specific Quality of Life Questionnaire Version 2.1 (MSQ v2.1)

End point description:

MSQ v2.1 is a health status instrument, with a 4-week recall period, developed to address physical and emotional limitations of specific concern to individuals with migraine. Addressing the impact of migraine on work or daily activities, relationships with family & friends, leisure time, productivity, concentration, energy, tiredness & feelings. It consists of 14 items that address 3 domains:(1) Role Function-Restrictive (items 1-7);(2) Role Function- Preventive (items 8-11);&(3) Emotional Function (items 12-14).Response options range from "none of the time" (value 1) to "all of the time" (value 6),& are reverse-recoded (value 6 to 1) before the domain scores are calculated. Total raw scores for each domain is the sum of the final item value for all of the items in that domain. After the total raw score is computed for each domain, they are transformed to a 0-100 scale with higher scores indicating a better health status & a positive change in scores reflecting functional improvement.

End point type	Secondary

End point timeframe:

Baseline, Month 3

APD: All randomized participants who received at least one dose of study drug and had a post baseline value at Month 3.

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	223		
Units: score on a scale				
least squares mean (standard error)	10.86 (± 1.34)	23.21 (± 1.35)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg

Number of subjects included in analysis	445
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [1]
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	12.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.19
upper limit	15.87
Variability estimate	Standard error of the mean
Dispersion value	1.7

Notes:

[1] - LS Mean was calculated using MMRM model with treatment, pooled country, month, treatment by month, baseline, and baseline by month as fixed effects.

Secondary: Mean Change from Baseline in the Role Function-Restrictive Domain Score of the Migraine-Specific Quality of Life Questionnaire Version 2.1 (MSQ v2.1) in Participants with Episodic Migraine

End point title	Mean Change from Baseline in the Role Function-Restrictive Domain Score of the Migraine-Specific Quality of Life Questionnaire Version 2.1 (MSQ v2.1) in Participants with Episodic Migraine

End point description:

MSQ v2.1 is a health status instrument, with a 4-week recall period, developed to address physical and emotional limitations of specific concern to individuals with migraine. Addressing the impact of migraine on work or daily activities, relationships with family & friends, leisure time, productivity, concentration, energy, tiredness & feelings. It consists of 14 items that address 3 domains:(1) Role Function-Restrictive (items 1-7);(2) Role Function- Preventive (items 8-11);&(3) Emotional Function (items 12-14).Response options range from "none of the time" (value 1) to "all of the time" (value 6),& are reverse-recoded (value 6 to 1) before the domain scores are calculated. Total raw scores for each domain is the sum of the final item value for all of the items in that domain. After the total raw score is computed for each domain, they are transformed to a 0-100 scale with higher scores indicating a better health status & a positive change in scores reflecting functional improvement.

End point type	Secondary

End point timeframe:

Baseline, Month 3

APD: All randomized episodic migraine participants who received at least one dose of study drug and had a post baseline value at Month 3.

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	135		
Units: score on a scale				
least squares mean (standard error)	11.88 (± 1.80)	23.39 (± 1.79)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	262
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [2]
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	11.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.14
upper limit	15.89
Variability estimate	Standard error of the mean
Dispersion value	2.22

Notes:

[2] - LS Mean was calculated using MMRM model with treatment, pooled country, month, treatment by month, baseline, and baseline by month as fixed effects.

Secondary: Percentage of Participants With Episodic Migraine with ≥75% Reduction from Baseline in Monthly Migraine Headache Days

End point title	Percentage of Participants With Episodic Migraine with ≥75% Reduction from Baseline in Monthly Migraine Headache Days

End point description:

MHD: A calendar day on which a migraine headache or probable migraine headache occurred.

Overall mean percentage across months 1 through 3 of patients with at least a 75% reduction in monthly MHDs from baseline using a categorical pseudo likelihood-based repeated measures model for binary responder indicator with fixed, categorical effects of treatment, month, treatment by month, and continuous, fixed covariate of baseline monthly MHD.

APD: All randomized episodic migraine participants who received at least one dose of study drug and had baseline and at least one post baseline value.

End point type	Secondary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	137		
Units: Percentage of Participants				
number (confidence interval 95%)	3.7 (1.6 to 8.2)	18.4 (13.9 to 23.9)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg

Number of subjects included in analysis	269
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0001
Method	Pseudo likelihood-based repeated measure
Parameter estimate	Odds ratio (OR)
Point estimate	5.878
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.374
upper limit	14.554

Secondary: Percentage of Participants With Episodic Migraine With 100% Reduction From Baseline in Monthly Migraine Headache Days

End point title	Percentage of Participants With Episodic Migraine With 100% Reduction From Baseline in Monthly Migraine Headache Days

End point description:

MHD: A calendar day on which a migraine headache or probable migraine headache occurred.

Overall mean percentage across months 1 through 3 of patients with 100% reduction in monthly MHDs from baseline using a categorical pseudo likelihood-based repeated measures model for binary responder indicator with fixed, categorical effects of treatment, month, treatment by month, and continuous, fixed covariate of baseline monthly MHD.

APD: All randomized episodic migraine participants who received at least one dose of study drug and had baseline and at least one post baseline value.

End point type	Secondary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	137		
Units: Percentage of Participants				
number (confidence interval 95%)	0.00 (0.00 to 0.00)	7.7 (4.7 to 12.3)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg

Number of subjects included in analysis	269
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [3]
Method	Pseudo likelihood-based repeated measure
Parameter estimate	Odds ratio (OR)
Point estimate	999.999
Confidence interval	
level	95 %
sides	2-sided
lower limit	548.706
upper limit	999.999

Notes:

[3] - Estimated value and upper bound are >999.999

Secondary: Percentage of Participants with ≥75% Reduction from Baseline in Monthly Migraine Headache Days

End point title	Percentage of Participants with ≥75% Reduction from Baseline in Monthly Migraine Headache Days

End point description:

MHD: A calendar day on which a migraine headache or probable migraine headache occurred.

Overall mean percentage across months 1 through 3 of patients with at least a 75% reduction in monthly MHDs from baseline using a categorical pseudo likelihood-based repeated measures model for binary responder indicator with fixed, categorical effects of treatment, month, treatment by month, and continuous, fixed covariate of baseline monthly MHD.

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

End point type	Secondary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	228	230		
Units: Percentage of Participants				
number (confidence interval 95%)	3.3 (1.7 to 6.3)	14.5 (10.9 to 19.0)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg

Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	pseudo likelihood-based repeated measure
Parameter estimate	Odds ratio (OR)
Point estimate	5.012
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.352
upper limit	10.679

Secondary: Percentage of Participants with 100% Reduction from Baseline in Monthly Migraine Headache Days

End point title	Percentage of Participants with 100% Reduction from Baseline in Monthly Migraine Headache Days

End point description:

MHD: A calendar day on which a migraine headache or probable migraine headache occurred.

Overall mean percentage across months 1 through 3 of patients with 100% reduction in monthly MHDs from baseline using a categorical pseudo likelihood-based repeated measures model for binary responder indicator with fixed, categorical effects of treatment, month, treatment by month, and continuous, fixed covariate of baseline monthly MHD

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

End point type	Secondary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	228	230		
Units: Percentage of Participants				
number (confidence interval 95%)	0.000 (0.000 to 0.000)	4.9 (2.8 to 8.6)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg

Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [4]
Method	Pseudo likelihood-based repeated measure
Parameter estimate	Odds ratio (OR)
Point estimate	999.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	999.99
upper limit	999.99

Notes:

[4] - Point estimate, upper limit and lower limit are >999.99

Secondary: Overall Mean Change from Baseline in the Number of Monthly Days with Acute Headache Medication Use

End point title	Overall Mean Change from Baseline in the Number of Monthly Days with Acute Headache Medication Use

End point description:

Overall mean is derived from the average of months 1 to 3 from Mixed model repeated measures (MMRM) model. Least square (LS) Mean was calculated using MMRM model with treatment, pooled country, month, treatment by month, baseline, and baseline by month as fixed effects.

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

End point type	Secondary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	228	230		
Units: Days				
least squares mean (standard error)	-0.80 (± 0.31)	-4.19 (± 0.32)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-3.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.14
upper limit	-2.65
Variability estimate	Standard error of the mean
Dispersion value	0.38

Secondary: Overall Mean Change from Baseline in the Number of Monthly Headache Days

End point title	Overall Mean Change from Baseline in the Number of Monthly Headache Days

End point description:

Headache Day: A calendar day on which any type of headache occurred (including migraine, probable migraine, and non-migraine headache).

Overall mean is derived from the average of months 1 to 3 from MMRM model. Least square (LS) Mean was calculated using MMRM model with treatment, pooled country, month, treatment by month, baseline, and baseline by month as fixed effects.

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

End point type	Secondary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	228	230		
Units: Days				
least squares mean (standard error)	-1.05 (± 0.36)	-4.18 (± 0.35)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	458
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-3.13

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.96
upper limit	-2.29
Variability estimate	Standard error of the mean
Dispersion value	0.42

Secondary: Mean Change from Baseline in the Migraine Disability Assessment Test (MIDAS) Total Score

End point title	Mean Change from Baseline in the Migraine Disability Assessment Test (MIDAS) Total Score

End point description:

The MIDAS is a participant-rated scale which was designed to quantify headache-related disability over a 3-month period. This instrument consists of five items that reflect the number of days reported as missed or with reduced productivity at work or home, and the number of days of missed social events. Each item has a numeric response range from 0 to 90 days, if days are missed from work or home they are not counted as days with reduced productivity at work or home. The numeric responses are summed to produce a total score ranging from 0 to 270, in which a higher value is indicative of more disability.
LS mean was calculated using analysis of covariance (ANCOVA) with last observation carried forward (LOCF), with baseline, pooled country, baseline migraine frequency category, and treatment as fixed effects.
APD: All randomized participants who received at least one dose of study drug and had a post baseline value at Month 3.

End point type	Secondary

End point timeframe:

Baseline, Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	225	228		
Units: score on a scale				
least squares mean (standard error)	-3.295 (± 3.2834)	-21.097 (± 3.3164)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	453
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA

Secondary: Mean Change from Baseline in the 4-item Migraine Interictal Burden Scale (MIBS-4)

End point title	Mean Change from Baseline in the 4-item Migraine Interictal Burden Scale (MIBS-4)

End point description:

MIBS-4 is a self-administered scale that measures the burden related to headache in the time between attacks. The instrument consists of 4 items that address disruption at work and school, diminished family and social life, difficulty planning, and emotional difficulty. The questionnaire specifically asks about the effect of the disease over the past 4 weeks on days without a headache attack. Response options include: don't know/not applicable (0), never (0), rarely (1), some of the time (2), much of the time (3), or most or all of the time (3). Each responses associated numerical score are summed across all 4 items resulting in a total score ranging from 0 to 12, and the level of interictal burden being categorized into the following: 0 for none, 1-2 mild, 3-4 moderate, and >5 severe. LS mean was calculated using MMRM model with fixed effects of treatment, pooled country, baseline migraine frequency category, month, treatment by month as fixed effects.

End point type	Secondary

End point timeframe:

Baseline, Month 3

APD: All randomized participants who received at least one dose of study drug and had a post baseline value at Month 3.

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	223		
Units: score on a scale				
least squares mean (standard error)	-0.78 (± 0.21)	-1.83 (± 0.21)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	445
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.58
upper limit	-0.54
Variability estimate	Standard error of the mean
Dispersion value	0.27

Secondary: Mean Change from Baseline in the Work Productivity and Activity Impairment Questionnaire (WPAI)

End point title	Mean Change from Baseline in the Work Productivity and Activity Impairment Questionnaire (WPAI)

End point description:

The WPAI Questionnaire is a patient-reported instrument developed to measure the impact on work productivity and regular activities attributable to a specific health problem (migraine). Recall period is the past 7 days. It contains 6 items that measure: 1) employment status, 2) hours missed from work due to the specific health problem, 3) hours missed from work for other reasons, 4) hours actually worked, 5) degree health affected productivity while working, and 6) degree health affected productivity in regular unpaid activities. Four scores are calculated from the responses to these 6 items: absenteeism, presenteeism, work productivity loss, and activity impairment. Scores are calculated as impairment percentages (0-100%), with higher numbers indicating greater impairment and less productivity, i.e, worse outcomes. LS mean was calculated using ANCOVA with LOCF with baseline, pooled country, baseline migraine frequency category, and treatment as fixed effects.

End point type	Secondary

End point timeframe:

Baseline, Month 3

APD: All randomized participants who received at least one dose of study drug and had a post baseline value at Month 3.

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	225	227		
Units: score on a scale				
least squares mean (standard error)				
Activity Impairment (n = 225,227)	-8.644 (± 1.9195)	-20.713 (± 1.9537)		
Absenteeism (n = 145, 148)	-2.900 (± 1.2436)	-4.224 (± 1.2929)		
Presenteeism (n = 141, 147)	-2.564 (± 2.3222)	-12.504 (± 2.3705)		
Work Impairment (n = 145, 148)	-3.457 (± 2.4098)	-14.307 (± 2.5148)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Activity Impairment.

Comparison groups	Placebo v Galcanezumab 120mg

Number of subjects included in analysis	452
Analysis specification	Pre-specified
Analysis type	superiority[5]
P-value	< 0.0001
Method	ANCOVA

Notes:

[5] - Activitiy Impairment.

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Absenteeism.

Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	452
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	= 0.388
Method	ANCOVA

Notes:

[6] - Absenteeism.

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Presenteeism.

Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	452
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	= 0.0004
Method	ANCOVA

Notes:

[7] - Presenteeism.

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Work Impairment.

Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	452
Analysis specification	Pre-specified
Analysis type	superiority[8]
P-value	= 0.0003
Method	ANCOVA

Notes:

[8] - Work Impairment.

Secondary: Mean Change from Baseline in the Patient Global Impression of Severity (PGI-S)

End point title	Mean Change from Baseline in the Patient Global Impression of Severity (PGI-S)

End point description:

The PGI-S is a patient-rated instrument that measures illness severity. For this study, the patient was instructed as follows: "Considering migraine as a chronic condition, how would you rate your level of illness?" The PGI-S includes a range of possible responses, from 1 ("normal, not at all ill") to 7 ("extremely ill"). LS mean was calculated using ANCOVA with LOCF with baseline, pooled country, baseline migraine frequency category, and treatment as fixed effects.

APD: All randomized participants who received at least one dose of study drug and had a post baseline value at Month 3.

End point type	Secondary

End point timeframe:

Baseline, Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	225	228		
Units: score on a scale				
least squares mean (standard error)	-0.283 (± 0.0863)	-0.664 (± 0.0873)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	453
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	ANCOVA

Secondary: Mean Change from Baseline in the European Quality of Life Questionnaire 5 Dimensions 5 Levels (EQ-5D-5L) - Health State Index (US)

End point title	Mean Change from Baseline in the European Quality of Life Questionnaire 5 Dimensions 5 Levels (EQ-5D-5L) - Health State Index (US)

End point description:

EQ-5D-5L is a 2-part questionnaire that assesses general health status for 'today'. The first part is comprised of the following 5 participant-reported dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The responses are used to derive the health state index scores using country-specific algorithms, with scores ranging from less than 0 (where zero is a health state equivalent to death; negative values are valued as worse than dead) to 1 (perfect health). Index values were calculated using the US algorithm (-0.109 to 1). A higher score indicates better health state. LS mean was calculated using ANCOVA with LOCF with baseline, pooled country, baseline migraine frequency category, and treatment as fixed effects.

APD: All randomized participants who received at least one dose of study drug and had a post baseline value at Month 3.

End point type	Secondary

End point timeframe:

Baseline, Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	225	227		
Units: score on a scale				
least squares mean (standard error)	-0.002 (± 0.0079)	0.013 (± 0.0080)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	452
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1267
Method	ANCOVA

Secondary: Mean Change from Baseline in the European Quality of Life Questionnaire 5 Dimensions 5 Levels (EQ-5D-5L) - Health State Index (UK)

End point title	Mean Change from Baseline in the European Quality of Life Questionnaire 5 Dimensions 5 Levels (EQ-5D-5L) - Health State Index (UK)

End point description:

EQ-5D-5L is a 2-part questionnaire that assesses general health status for 'today'. The first part is comprised of the following 5 participant-reported dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The responses are used to derive the health state index scores using country-specific algorithms, with scores ranging from less than 0 (where zero is a health state equivalent to death; negative values are valued as worse than dead) to 1 (perfect health). Index values were calculated using the UK algorithm (-0.594 to 1). LS mean was calculated using ANCOVA with LOCF with baseline, pooled country, baseline migraine frequency category, and treatment as fixed effects.

APD: All randomized participants who received at least one dose of study drug and had a post baseline value at Month 3.

End point type	Secondary

End point timeframe:

Baseline, Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	225	227		
Units: score on a scale				
least squares mean (standard error)	-0.001 (± 0.0109)	0.017 (± 0.0110)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	452
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.163
Method	ANCOVA

Secondary: Mean Change from Baseline in the European Quality of Life Questionnaire 5 Dimensions 5 Levels (EQ-5D-5L) - VAS Score

End point title	Mean Change from Baseline in the European Quality of Life Questionnaire 5 Dimensions 5 Levels (EQ-5D-5L) - VAS Score

End point description:

EQ-5D-5L is a 2-part questionnaire that assesses general health status 'today'. . The second part is assessed using a visual analog scale (VAS) on which the patient rates their perceived health state, ranging from 0 (the worst health you can imagine) to 100 (the best health you can imagine). LS mean was calculated using ANCOVA with LOCF with baseline, pooled country, baseline migraine frequency category, and treatment as fixed effects.

APD: All randomized participants who received at least one dose of study drug and had a post baseline value at Month 3.

End point type	Secondary

End point timeframe:

Baseline, Month 3

End point values	Placebo	Galcanezumab 120mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	225	227		
Units: mm				
least squares mean (standard error)	-0.086 (± 1.2916)	3.376 (± 1.3080)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	452
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0277
Method	ANCOVA

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Entire Study	
Adverse event reporting additional description:	
I5Q-MC-CGAW	
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: -	
Reporting group title	Galcanezumab 120mg - Double-Blind Treatment Phase
Reporting group description: -	
Reporting group title	Placebo/Galcanezumab 120mg - Open-Label Treatment Phase
Reporting group description: -	
Reporting group title	Galcanezumab 120mg/Galcanezumab 120mg - Open-Label Treatment
Reporting group description: -	

Serious adverse events	Placebo - Double-Blind Treatment Phase	Galcanezumab 120mg - Double-Blind Treatment Phase	Placebo/Galcanezumab 120mg - Open-Label Treatment Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 230 (0.87%)	2 / 232 (0.86%)	6 / 225 (2.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
arthropod bite			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 230 (0.00%)	0 / 232 (0.00%)	1 / 225 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 230 (0.00%)	0 / 232 (0.00%)	1 / 225 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

lower limb fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 230 (0.43%)	0 / 232 (0.00%)	0 / 225 (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
Vascular disorders			
behcet's syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 230 (0.43%)	0 / 232 (0.00%)	0 / 225 (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			
hemiplegia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 230 (0.00%)	0 / 232 (0.00%)	1 / 225 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 230 (0.00%)	0 / 232 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 230 (0.00%)	0 / 232 (0.00%)	1 / 225 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
haemorrhoids			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 230 (0.00%)	1 / 232 (0.43%)	0 / 225 (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

inguinal hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 230 (0.00%)	0 / 232 (0.00%)	1 / 225 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
ovarian cyst ruptured			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 202 (0.00%)	0 / 195 (0.00%)	0 / 197 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
pulmonary embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 230 (0.00%)	0 / 232 (0.00%)	1 / 225 (0.44%)
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			
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 230 (0.00%)	0 / 232 (0.00%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 230 (0.00%)	1 / 232 (0.43%)	0 / 225 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Galcanezumab 120mg/Galcanezumab 120mg - Open-Label Treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 224 (1.34%)		
number of deaths (all causes)	0		

number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
arthropod bite			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 224 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
injury			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 224 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
lower limb fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 224 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
behcet's syndrome			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 224 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
hemiplegia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 224 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 224 (0.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 224 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
haemorrhoids			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 224 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
inguinal hernia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 224 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
ovarian cyst ruptured			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	1 / 187 (0.53%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
pulmonary embolism			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 224 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
pneumonia			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 224 (0.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
tonsillitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 224 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Notes:

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

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

Non-serious adverse events	Placebo - Double-Blind Treatment Phase	Galcanezumab 120mg - Double-Blind Treatment Phase	Placebo/Galcanezumab 120mg - Open-Label Treatment Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 230 (13.48%)	21 / 232 (9.05%)	19 / 225 (8.44%)
General disorders and administration site conditions			
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	13 / 230 (5.65%)	5 / 232 (2.16%)	11 / 225 (4.89%)
occurrences (all)	30	7	19
Infections and infestations			
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	21 / 230 (9.13%)	16 / 232 (6.90%)	11 / 225 (4.89%)
occurrences (all)	24	17	11

Non-serious adverse events	Galcanezumab 120mg/Galcanezumab 120mg - Open-Label Treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 224 (5.80%)		
General disorders and administration site conditions			

injection site pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all)	 5 / 224 (2.23%) 7		
Infections and infestations nasopharyngitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all)	 8 / 224 (3.57%) 9		

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

None reported