Clinical trial results:
A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of LY2951742 in Patients with Chronic Migraine - the REGAIN Study.

Summary

EudraCT number	2015-001883-21
Trial protocol	NL GB CZ DE IT
Global end of trial date	14 July 2021

Results information

Result version number	v1 (current)
This version publication date	11 May 2022
First version publication date	11 May 2022

Trial information

Trial identification

Sponsor protocol code	I5Q-MC-CGAI

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02614261
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 15769

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 July 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 July 2021
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 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	30 November 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	United States: 629
Country: Number of subjects enrolled	Argentina: 82
Country: Number of subjects enrolled	Canada: 15
Country: Number of subjects enrolled	Czechia: 45
Country: Number of subjects enrolled	Germany: 54
Country: Number of subjects enrolled	Spain: 50
Country: Number of subjects enrolled	United Kingdom: 31
Country: Number of subjects enrolled	Israel: 40
Country: Number of subjects enrolled	Italy: 56
Country: Number of subjects enrolled	Mexico: 24
Country: Number of subjects enrolled	Netherlands: 43
Country: Number of subjects enrolled	Taiwan: 48
Worldwide total number of subjects	1117
EEA total number of subjects	248

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)	4
Adults (18-64 years)	1104
From 65 to 84 years	9
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Main study: This randomised part of study was conducted in 3 phases: a 3-month double-blind treatment phase followed by an optional 9-month open-label extension phase and a 4-month follow-up phase.

Israel addendum: Participants in Israel who completed all phases in main study, benefited from galcanezumab and (cont'd)..

Pre-assignment

Screening details:

..(cont'd) did not have alternative treatment options available were provided continued-access to treatment where safety was monitored.

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Placebo

Arm description:

Double-blind treatment phase: Participants received placebo once a month by subcutaneous (SC) injection for 3 months.

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:

Placebo once a month by subcutaneous (SC) injection for 3 months.

Arm title	Galcanezumab 120mg

Arm description:

Double-blind treatment phase: Participants received loading dose of 240 mg of galcanezumab at first dosing visit followed 120 mg galcanezumab once a month by subcutaneous injection for 2 months.

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:

240 milligrams (mg) of galcanezumab at first dosing visit followed 120 mg galcanezumab once a month by subcutaneous injection for 2 months.

Arm title	Galcanezumab 240mg

Arm description:

Double-blind treatment phase: Participants received 240 mg of galcanezumab once a month by subcutaneous injection for 3 months.

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:

240 mg of galcanezumab once a month by subcutaneous injection for 3 months.

Number of subjects in period 1	Placebo	Galcanezumab 120mg	Galcanezumab 240mg
Started	559	279	279
Received at least one dose of study drug	558	278	277
Completed	509	262	266
Not completed	50	17	13
Physician decision	2	1	1
Consent withdrawn by subject	20	5	7
Screen Failure	-	1	2
Adverse event, non-fatal	7	3	2
Pregnancy	2	2	-
Lost to follow-up	9	4	1
Lack of efficacy	4	-	-
Protocol deviation	6	1	-

Period 2

Period 2 title	Open-Label Extension 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:

Open-label extension phase: After completion of double-blind phase, participants had an option to enter open-label extension phase where they receive 240 milligram (mg) galcanezumab SC at first month, 120mg at second month followed by 120mg or 240mg once a month (at the discretion of the investigator) for the remaining 7 months.

Arm type	Placebo

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:

240 mg galcanezumab SC at first month, 120mg at second month followed by 120mg or 240mg once a month (at the discretion of the investigator) for the remaining 7 months.

Arm title	Galcanezumab 120mg

Arm description:

Open-label extension phase: After completion of double-blind phase, participants had an option to enter open-label extension phase where they received 240mg galcanezumab SC at first month, 120mg at second month followed by 120mg or 240mg once a month (at the discretion of the investigator) for the remaining 7 months.

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:

240mg galcanezumab SC at first month, 120mg at second month followed by 120mg or 240mg once a month (at the discretion of the investigator) for the remaining 7 months.

Arm title	Galcanezumab 240mg

Arm description:

Open-label extension phase: After completion of double-blind phase, participants had an option to enter open-label extension phase where they received 240mg galcanezumab SC at first month, 120mg at second month followed by 120mg or 240mg once a month (at the discretion of the investigator) for the remaining 7 months.

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:

240mg galcanezumab SC at first month, 120mg at second month followed by 120mg or 240mg once a month (at the discretion of the investigator) for the remaining 7 months.

Number of subjects in period 2	Placebo	Galcanezumab 120mg	Galcanezumab 240mg
Started	501	259	262
Completed	413	204	208
Not completed	88	55	54
Physician decision	2	-	-
Consent withdrawn by subject	30	18	18
Adverse event, non-fatal	23	12	11
Pregnancy	1	2	1
Lost to follow-up	15	7	9

Lack of efficacy	14	12	14
Protocol deviation	3	4	1

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

Arms

Are arms mutually exclusive?	No
Arm title	Placebo

Arm description:

Follow-up phase: After completion or discontinuation from double-blind or open-label extension phases, participants entered follow-up phase where they were observed for 4 months. No treatments administered.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Galcanezumab 120mg

Arm description:

Follow-up phase: After completion or discontinuation from double-blind or open-label extension phases, participants entered follow-up phase where they were observed for 4 months. No treatments administered.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Galcanezumab 240mg

Arm description:

Follow-up phase: After completion or discontinuation from double-blind or open-label extension phases, participants entered follow-up phase where they were observed for 4 months. No treatments administered.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 3	Placebo	Galcanezumab 120mg	Galcanezumab 240mg
Started	453	228	231
Entered From Double-blind Phase	15 [1]	5 [2]	3 [3]
Entered From Open-label Extension Phase	438	223	228

Completed	421	217	217
Not completed	32	11	14
Physician decision	5	1	-
Consent withdrawn by subject	12	4	11
Adverse event, non-fatal	2	-	1
Pregnancy	-	1	-
Lost to follow-up	12	5	2
Protocol deviation	1	-	-

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Breakdown of participants who entered follow-up phase from Double-blind phase, Open-label Extension Phase.
[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Breakdown of participants who entered follow-up phase from Double-blind phase, Open-label Extension Phase.
[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Breakdown of participants who entered follow-up phase from Double-blind phase, Open-label Extension Phase.

Period 4

Period 4 title	Israel Addendum
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Israel Addendum

Arm description:

Eligible participants from main study were enrolled in Israel addendum. Participants received 120mg or 240mg galcanezumab SC once a month, at the discretion of the investigator, for up to 3 years or until Israel's Ministry of Health's conditions for continued access cease to be met, whichever occurs first.

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:

120mg or 240mg galcanezumab SC once a month, at the discretion of the investigator, for up to 3 years or until Israel's Ministry of Health's conditions for continued access cease to be met, whichever occurs first.

Number of subjects in period 4	Israel Addendum
Started	29
Completed	25
Not completed	4
Consent withdrawn by subject	4

Baseline characteristics

Reporting groups

Reporting group title	Double-Blind Treatment Phase

Reporting group description: -

Reporting group values	Double-Blind Treatment Phase	Total	
Number of subjects	1117	1117	
Age categorical Units: Subjects			
Adolescents (12-17 years)	4	4	
Adults (18-64 years)	1104	1104	
From 65-84 years	9	9	
Age continuous Units: years			
arithmetic mean	40.98		
standard deviation	± 12.11	-	
Gender categorical Units: Subjects			
Female	950	950	
Male	167	167	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	256	256	
Not Hispanic or Latino	792	792	
Unknown or Not Reported	69	69	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	6	6	
Asian	54	54	
Native Hawaiian or Other Pacific Islander	1	1	
Black or African American	72	72	
White	882	882	
More than one race	101	101	
Unknown or Not Reported	1	1	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Double-blind treatment phase: Participants received placebo once a month by subcutaneous (SC) injection for 3 months.	

Reporting group title	Galcanezumab 120mg
Reporting group description:	
Double-blind treatment phase: Participants received loading dose of 240 mg of galcanezumab at first dosing visit followed 120 mg galcanezumab once a month by subcutaneous injection for 2 months.	

Reporting group title	Galcanezumab 240mg
Reporting group description:	
Double-blind treatment phase: Participants received 240 mg of galcanezumab once a month by subcutaneous injection for 3 months.	

Reporting group title	Placebo
Reporting group description:	
Open-label extension phase: After completion of double-blind phase, participants had an option to enter open-label extension phase where they receive 240 milligram (mg) galcanezumab SC at first month, 120mg at second month followed by 120mg or 240mg once a month (at the discretion of the investigator) for the remaining 7 months.	

Reporting group title	Galcanezumab 120mg
Reporting group description:	
Open-label extension phase: After completion of double-blind phase, participants had an option to enter open-label extension phase where they received 240mg galcanezumab SC at first month, 120mg at second month followed by 120mg or 240mg once a month (at the discretion of the investigator) for the remaining 7 months.	

Reporting group title	Galcanezumab 240mg
Reporting group description:	
Open-label extension phase: After completion of double-blind phase, participants had an option to enter open-label extension phase where they received 240mg galcanezumab SC at first month, 120mg at second month followed by 120mg or 240mg once a month (at the discretion of the investigator) for the remaining 7 months.	

Reporting group title	Placebo
Reporting group description:	
Follow-up phase: After completion or discontinuation from double-blind or open-label extension phases, participants entered follow-up phase where they were observed for 4 months. No treatments administered.	

Reporting group title	Galcanezumab 120mg
Reporting group description:	
Follow-up phase: After completion or discontinuation from double-blind or open-label extension phases, participants entered follow-up phase where they were observed for 4 months. No treatments administered.	

Reporting group title	Galcanezumab 240mg
Reporting group description:	
Follow-up phase: After completion or discontinuation from double-blind or open-label extension phases, participants entered follow-up phase where they were observed for 4 months. No treatments administered.	

Reporting group title	Israel Addendum
Reporting group description:	
Eligible participants from main study were enrolled in Israel addendum. Participants received 120mg or 240mg galcanezumab SC once a month, at the discretion of the investigator, for up to 3 years or until Israel's Ministry of Health's conditions for continued access cease to be met, whichever occurs first.	

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

End point title	Overall Mean Change from Baseline in the Number of Monthly Migraine Headache Days (MHD)

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 mixed model repeated measures (MMRM) model. Least square(LS) Mean was calculated using MMRM model with treatment, pooled country, baseline medication overuse, concurrent prophylaxis use, month, treatment by month, baseline, and baseline by month as fixed effects.
Analysis Population Description (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	Primary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg	Galcanezumab 240mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	538	273	274	
Units: Migraine Headache Days per Month				
least squares mean (standard error)	-2.74 (± 0.36)	-4.83 (± 0.44)	-4.62 (± 0.43)	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	811
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-2.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.92
upper limit	-1.26
Variability estimate	Standard error of the mean
Dispersion value	0.42

	Statistical analysis 1

Statistical analysis title	
Comparison groups	Placebo v Galcanezumab 240mg
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-1.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.71
upper limit	-1.05
Variability estimate	Standard error of the mean
Dispersion value	0.42

Secondary: Number of Participants with Reduction from Baseline ≥50%, ≥75% and 100% in Monthly Migraine Headache Days

End point title	Number of Participants with Reduction from Baseline ≥50%, ≥75% and 100% in Monthly Migraine Headache Days

End point description:

MHD: A calendar day on which a migraine headache or probable migraine headache occurred.
APD: All randomized participants who received at least one dose of study drug and had baseline and month 3 measurement.

End point type	Secondary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg	Galcanezumab 240mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	498	256	262	
Units: participants				
≥50%	123	90	97	
≥75%	44	34	40	
≥100%	8	4	8	

Statistical analyses

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Reduction from Baseline ≥50%,

Comparison groups	Placebo v Galcanezumab 120mg

Number of subjects included in analysis	754
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	= 0.004
Method	CPRMM
Parameter estimate	Odds ratio (OR)
Point estimate	1.623
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.167
upper limit	2.256

Notes:

[1] - Reduction from Baseline ≥50%,

Statistical analysis title	Statistical analysis 2
Statistical analysis description: Reduction from Baseline ≥50%	
Comparison groups	Placebo v Galcanezumab 240mg
Number of subjects included in analysis	760
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	< 0.001
Method	CPRMM
Parameter estimate	Odds ratio (OR)
Point estimate	1.788
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.291
upper limit	2.474

Notes:

[2] - Reduction from Baseline ≥50%

Statistical analysis title	Statistical analysis 2
Statistical analysis description: Reduction from Baseline ≥75%	
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	754
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.102
Method	CPRMM
Parameter estimate	Odds ratio (OR)
Point estimate	1.498
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.923
upper limit	2.43

Notes:
[3] - Reduction from Baseline ≥75%

Statistical analysis title	Statistical analysis 2
Statistical analysis description: Reduction from Baseline ≥75%	
Comparison groups	Placebo v Galcanezumab 240mg
Number of subjects included in analysis	760
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	= 0.011
Method	CPRMM
Parameter estimate	Odds ratio (OR)
Point estimate	1.819
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.146
upper limit	2.888

Notes:
[4] - Reduction from Baseline ≥75%

Statistical analysis title	Statistical analysis 2
Statistical analysis description: Reduction from Baseline ≥100%	
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	754
Analysis specification	Pre-specified
Analysis type	superiority[5]
P-value	= 0.729
Method	CPRMM
Parameter estimate	Odds ratio (OR)
Point estimate	0.761
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.163
upper limit	3.563

Notes:
[5] - Reduction from Baseline ≥100%

Statistical analysis title	Statistical analysis 2
Statistical analysis description: Reduction from Baseline ≥100%	
Comparison groups	Placebo v Galcanezumab 240mg

Number of subjects included in analysis	760
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	= 0.276
Method	CPRMM
Parameter estimate	Odds ratio (OR)
Point estimate	1.897
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	5.998

Notes:

[6] - Reduction from Baseline ≥100%

Secondary: Mean Change from Baseline in the Migraine-Specific Quality of Life Questionnaire (MSQ) Role-function Restrictive Domain

End point title	Mean Change from Baseline in the Migraine-Specific Quality of Life Questionnaire (MSQ) Role-function Restrictive Domain

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. 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. APD: All randomized participants who received at least one dose of study drug and had baseline and month 3 measurement.

End point type	Secondary

End point timeframe:

Baseline, Month 3

End point values	Placebo	Galcanezumab 120mg	Galcanezumab 240mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	494	252	253	
Units: units on a scale				
least squares mean (standard error)	16.76 (± 1.18)	21.81 (± 1.41)	23.05 (± 1.63)	

Statistical analyses

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v Galcanezumab 120mg

Number of subjects included in analysis	746
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	5.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.12
upper limit	7.99
Variability estimate	Standard error of the mean
Dispersion value	1.5

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v Galcanezumab 240mg
Number of subjects included in analysis	747
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	6.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.03
upper limit	9.55
Variability estimate	Standard error of the mean
Dispersion value	1.66

Secondary: Overall Mean Change from Baseline in the Number of Monthly Migraine Headache Days Requiring Medication for the Acute Treatment of Migraine or Headache

End point title	Overall Mean Change from Baseline in the Number of Monthly Migraine Headache Days Requiring Medication for the Acute Treatment of Migraine or Headache

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 MMRM model. LSMean was calculated using MMRM model with treatment, pooled country, baseline medication overuse, concurrent prophylaxis use, 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 measurement.

End point type	Secondary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg	Galcanezumab 240mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	538	273	274	
Units: Days Per Month				
least squares mean (standard error)	-2.23 (± 0.33)	-4.74 (± 0.40)	-4.25 (± 0.40)	

Statistical analyses

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	811
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-2.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.27
upper limit	-1.76
Variability estimate	Standard error of the mean
Dispersion value	0.38

Statistical analysis title	Statistical analysis 4
Comparison groups	Galcanezumab 240mg v Placebo
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-2.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.77
upper limit	-1.26
Variability estimate	Standard error of the mean
Dispersion value	0.38

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

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

End point description:

PGI-S scale is a participant-rated instrument that measures participants own global impression of their illness severity. The participant was instructed as follows: "Considering migraine as a chronic condition, how would you rate your level of illness?" Response options were from 1 ("normal, not at all ill") to 7 ("extremely ill"). LSMean was calculated using MMRM model with treatment, pooled country, baseline medication overuse, concurrent prophylaxis use, 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 month 3 measurement.

End point type	Secondary

End point timeframe:

Baseline, Month 3

End point values	Placebo	Galcanezumab 120mg	Galcanezumab 240mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	494	252	253	
Units: units on a scale				
least squares mean (standard error)	-0.62 (± 0.08)	-0.76 (± 0.10)	-0.91 (± 0.10)	

Statistical analyses

Statistical analysis title	Statistical analysis 5
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	746
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.181
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.34
upper limit	0.06
Variability estimate	Standard error of the mean
Dispersion value	0.1

Statistical analysis title	Statistical analysis 5
Comparison groups	Placebo v Galcanezumab 240mg
Number of subjects included in analysis	747
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.48
upper limit	-0.08
Variability estimate	Standard error of the mean
Dispersion value	0.1

Secondary: Overall Mean Change from Baseline in Headache Hours

End point title	Overall Mean Change from Baseline in Headache Hours

End point description:

Overall mean is derived from the average of months 1 to 3 from MMRM model. LSMean was calculated using MMRM model with treatment, pooled country, baseline medication overuse, concurrent prophylaxis use, 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 & at least one post baseline measurement.

End point type	Secondary

End point timeframe:

Baseline, Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg	Galcanezumab 240mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	538	273	274	
Units: Headache Hours per Month				
least squares mean (standard error)	-13.44 (± 3.91)	-36.15 (± 4.74)	-31.53 (± 4.70)	

Statistical analyses

Statistical analysis title	Statistical analysis 6
Comparison groups	Placebo v Galcanezumab 120mg

Number of subjects included in analysis	811
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-22.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.74
upper limit	-13.69
Variability estimate	Standard error of the mean
Dispersion value	4.6

Statistical analysis title	Statistical analysis 6
Comparison groups	Galcanezumab 240mg v Placebo
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LSMean Difference
Point estimate	-18.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.09
upper limit	-9.09
Variability estimate	Standard error of the mean
Dispersion value	4.58

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

End point title	Mean Change from Baseline on 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 missing 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. LSMean was calculated using Analysis of covariance (ANCOVA) model with last observation carried forward (LOCF) with treatment, pooled country, baseline medication overuse, concurrent prophylaxis use, and baseline value 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 measurement.

End point type	Secondary

End point timeframe:
Baseline, Month 3

End point values	Placebo	Galcanezumab 120mg	Galcanezumab 240mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	504	254	258	
Units: units on a scale				
least squares mean (standard error)	-11.53 (± 3.38)	-20.27 (± 4.07)	-17.02 (± 4.05)	

Statistical analyses

Statistical analysis title	Statistical analysis 7
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	758
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.025
Method	ANCOVA
Parameter estimate	LSMean Difference
Point estimate	-8.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.39
upper limit	-1.08
Variability estimate	Standard error of the mean
Dispersion value	3.9

Statistical analysis title	Statistical analysis 7
Comparison groups	Placebo v Galcanezumab 240mg
Number of subjects included in analysis	762
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.157
Method	ANCOVA
Parameter estimate	LSMean Difference
Point estimate	-5.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.1
upper limit	2.12

Variability estimate	Standard error of the mean
Dispersion value	3.88

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

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

End point description:

A Treatment Emergent Anti-Drug Antibodies (TE ADA) evaluable participant is considered to be TE ADA+ if the participant 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 >= 20.
APD: All randomized participants who received at least one dose of study drug and had at least one non-missing test result for ADA for each of the baseline period and the post baseline period.

End point type	Secondary

End point timeframe:

Month 1 through Month 3

End point values	Placebo	Galcanezumab 120mg	Galcanezumab 240mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	535	264	272	
Units: participants	8	7	7	

Statistical analyses

Statistical analysis title	Statistical analysis 8
Comparison groups	Placebo v Galcanezumab 120mg
Number of subjects included in analysis	799
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.263
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 8
Comparison groups	Placebo v Galcanezumab 240mg
Number of subjects included in analysis	807
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.29
Method	Cochran-Mantel-Haenszel

Secondary: Pharmacokinetics (PK): Area Under the Concentration Time Curve (AUC) of Galcanezumab

End point title	Pharmacokinetics (PK): Area Under the Concentration Time Curve (AUC) of Galcanezumab[7]

End point description:

Pharmacokinetics (PK): Area Under the Concentration Time Curve (AUC) of Galcanezumab.
APD: Zero participants analyzed. AUC data was not collected as AUC was not pre-specified in protocol.

End point type	Secondary

End point timeframe:

Baseline through Month 3

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: PK outcomes only for active drug - Galcanezumab.

End point values	Galcanezumab 120mg	Galcanezumab 240mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[8]	0[9]		
Units: nanograms*hours per milliliter				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[8] - Zero participants analyzed. AUC data was not collected as AUC was not pre-specified in protocol.

[9] - Zero participants analyzed. AUC data was not collected as AUC was not pre-specified in protocol.

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Concentration of Calcitonin Gene-Related Peptide (CGRP)

End point title	Plasma Concentration of Calcitonin Gene-Related Peptide (CGRP)

End point description:

Plasma Concentration of Calcitonin Gene-Related Peptide (CGRP).
APD: All randomized participants who received at least one dose of study drug and had measurable plasma concentrations.

End point type	Secondary

End point timeframe:

Month 3

End point values	Placebo	Galcanezumab 120mg	Galcanezumab 240mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30	247	253	
Units: Nanogram per milliliter (ng/mL)				
arithmetic mean (standard deviation)	0.529 (± 0.612)	4.02 (± 1.70)	4.85 (± 1.76)	

Statistical analyses

No statistical analyses for this end point

Secondary: Serum concentrations of Galcanezumab

End point title	Serum concentrations of Galcanezumab[10]

End point description:

Serum concentrations of Galcanezumab
APD: All randomized participants who received at least one dose of Galcanezumab and had measurable serum concentrations.

End point type	Secondary

End point timeframe:

Month 3

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: PK outcomes only for active drug - Galcanezumab.

End point values	Galcanezumab 120mg	Galcanezumab 240mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248	254		
Units: Nanogram per milliliter (ng/mL)				
arithmetic mean (standard deviation)	16900 (± 7140)	29000 (± 11300)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Baseline to 16 months for main study plus additional 3 years if enrolled in Israel continued-access addendum.

Adverse event reporting additional description:

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

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Galcanezumab 120mg - Double-Blind Treatment Phase

Reporting group description:

Participants received loading dose of 240mg galcanezumab at first dosing visit followed by 120mg of galcanezumab once a month by subcutaneous injection for 2 months.
5 participants discontinued after receiving loading dose of 240mg. They were included under 240mg arm for safety analysis.

Reporting group title	Placebo - Double-Blind Treatment Phase

Reporting group description:

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

Reporting group title	Galcanezumab 240mg - Double-Blind Treatment Phase

Reporting group description:

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

Reporting group title	Galcanezumab 240mg/Galcanezumab - Open-Label Extension Phase

Reporting group description:

After completion of Galcanezumab 240mg double-blind phase, participants had an option to enter open-label extension phase where they received 240mg galcanezumab SC at first month, 120mg at second month followed by 120mg or 240mg once a month (at the discretion of the investigator) for the remaining 7 months.

Reporting group title	Galcanezumab 120mg/Galcanezumab - Open-Label Extension Phase

Reporting group description:

After completion of Galcanezumab 120mg double-blind phase, participants had an option to enter open-label extension phase where they received 240mg galcanezumab SC at first month, 120mg at second month followed by 120mg or 240mg once a month (at the discretion of the investigator) for the remaining 7 months.

Reporting group title	Placebo/Galcanezumab - Open-Label Extension Phase

Reporting group description: -

Reporting group title	Placebo - Follow-up Phase

Reporting group description:

Participants entered follow-up phase from placebo double-blind treatment phase and were observed for 4 months. No treatments administered.

Reporting group title	Galcanezumab 120mg - Follow-up Phase

Reporting group description:

Participants entered follow-up phase from Galcanezumab 120mg double-blind treatment phase and were observed for 4 months. No treatments administered.
1 participant discontinued from double-blind treatment phase after receiving 240mg loading dose and entered Follow-up phase. That participant was included under 240mg arm for safety analysis.

Reporting group title	Galcanezumab 240mg - Follow-up Phase

Reporting group description:

Participants entered follow-up phase from from Galcanezumab 240mg double-blind treatment phase and

were observed for 4 months. No treatments administered.

Reporting group title	Placebo/Galcanezumab - Follow-up Phase

Reporting group description:

Participants entered follow-up phase from Placebo/Galcanezumabopen-label extension phase and were observed for 4 months. No treatments administered.

Reporting group title	Galcanezumab 120mg/Galcanezumab - Follow-up Phase

Reporting group description:

Participants entered follow-up phase from Galcanezumab 120mg/Galcanezumab open-label extension phase and were observed for 4 months. No treatments administered.

Reporting group title	Galcanezumab 240mg/Galcanezumab - Follow-up Phase

Reporting group description:

Participants entered follow-up phase from Galcanezumab 240mg/Galcanezumab open-label extension phase and were observed for 4 months. No treatments administered.

Reporting group title	Israel Addendum

Reporting group description:

Eligible participants from main study were enrolled in Israel addendum. Participants received 120mg or 240mg galcanezumab SC once a month, at the discretion of the investigator, for up to 3 years or until Israel's Ministry of Health's conditions for continued access cease to be met, whichever occurs first.

Serious adverse events	Galcanezumab 120mg - Double-Blind Treatment Phase	Placebo - Double-Blind Treatment Phase	Galcanezumab 240mg - Double-Blind Treatment Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 273 (0.73%)	5 / 558 (0.90%)	4 / 282 (1.42%)
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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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 cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 273 (0.37%)	0 / 558 (0.00%)	0 / 282 (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
lung adenocarcinoma			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant nipple neoplasm			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 273 (0.37%)	0 / 558 (0.00%)	0 / 282 (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
oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tongue neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[1]	0 / 232 (0.00%)	0 / 483 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
varicose vein			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[2]	0 / 232 (0.00%)	1 / 483 (0.21%)	0 / 231 (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
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
swelling face			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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			
dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epistaxis			
alternative dictionary used:			

MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	1 / 558 (0.18%)	0 / 282 (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
haemoptysis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	1 / 282 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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			
foot fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin laceration			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
congenital diaphragmatic hernia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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			
acute myocardial infarction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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 failure congestive			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	1 / 558 (0.18%)	0 / 282 (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
ventricular extrasystoles			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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			
migraine			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
orthostatic intolerance			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seizure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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			
abdominal adhesions			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abdominal pain lower			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abdominal pain upper			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
alcoholic pancreatitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	1 / 558 (0.18%)	0 / 282 (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
gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	1 / 558 (0.18%)	0 / 282 (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
haematemesis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhoids			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hiatus hernia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	1 / 282 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
volvulus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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			
nephrolithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	1 / 282 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal colic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	1 / 282 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tubulointerstitial nephritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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 retention			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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			
intervertebral disc protrusion			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic tonsillitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
complicated appendicitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteomyelitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vestibular neuronitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic ketoacidosis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypokalaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	1 / 282 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Galcanezumab 240mg/Galcanezumab - Open-Label Extension Phase	Galcanezumab 120mg/Galcanezumab - Open-Label Extension Phase	Placebo/Galcanezumab - Open-Label Extension Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 262 (3.44%)	6 / 259 (2.32%)	16 / 501 (3.19%)
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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
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 cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung adenocarcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant nipple neoplasm			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	1 / 259 (0.39%)	0 / 501 (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
tongue neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[1]	0 / 214 (0.00%)	0 / 218 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
varicose vein			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[2]	0 / 214 (0.00%)	0 / 218 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
swelling face			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epistaxis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemoptysis			
alternative dictionary used:			

MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
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			
confusional state			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
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, poisoning and procedural complications			
foot fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
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 24.0			
subjects affected / exposed	0 / 262 (0.00%)	1 / 259 (0.39%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin laceration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	1 / 259 (0.39%)	0 / 501 (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
Congenital, familial and genetic disorders			
congenital diaphragmatic hernia			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 262 (0.38%)	0 / 259 (0.00%)	0 / 501 (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
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 262 (0.38%)	0 / 259 (0.00%)	0 / 501 (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
angina unstable			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 262 (0.38%)	0 / 259 (0.00%)	0 / 501 (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
cardiac failure congestive			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 262 (0.38%)	0 / 259 (0.00%)	0 / 501 (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
myocardial infarction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular extrasystoles			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
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			
migraine			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 262 (0.38%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
orthostatic intolerance			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	1 / 259 (0.39%)	0 / 501 (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
seizure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 262 (0.38%)	1 / 259 (0.39%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
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			
abdominal adhesions			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abdominal pain lower			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abdominal pain upper			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
alcoholic pancreatitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematemesis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemorrhoids			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hiatus hernia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 262 (0.38%)	0 / 259 (0.00%)	0 / 501 (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
nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pancreatitis acute			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
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 24.0			
subjects affected / exposed	1 / 262 (0.38%)	0 / 259 (0.00%)	0 / 501 (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
volvulus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	1 / 259 (0.39%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urticaria			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 262 (0.38%)	0 / 259 (0.00%)	0 / 501 (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
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal colic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tubulointerstitial nephritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 262 (0.38%)	0 / 259 (0.00%)	0 / 501 (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 retention			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
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			
intervertebral disc protrusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
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 24.0			

subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic tonsillitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
complicated appendicitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteomyelitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

upper respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	1 / 259 (0.39%)	0 / 501 (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
urinary tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	1 / 259 (0.39%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vestibular neuronitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic ketoacidosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 262 (0.38%)	0 / 259 (0.00%)	0 / 501 (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
hypokalaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo - Follow-up Phase	Galcanezumab 120mg - Follow-up Phase	Galcanezumab 240mg - Follow-up Phase

Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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 cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
lung adenocarcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
malignant nipple neoplasm			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
squamous cell carcinoma			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
tongue neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[1]	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
varicose vein			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[2]	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used:			

MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
swelling face			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
Respiratory, thoracic and mediastinal disorders			
dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
epistaxis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
haemoptysis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
pulmonary embolism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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			
confusional state			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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			
foot fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin laceration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
Congenital, familial and genetic disorders			
congenital diaphragmatic hernia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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			
acute myocardial infarction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
angina unstable			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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 failure congestive			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
myocardial infarction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
ventricular extrasystoles			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
Nervous system disorders			
migraine			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
orthostatic intolerance			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
seizure			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
Gastrointestinal disorders			
abdominal adhesions			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
abdominal pain lower			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
abdominal pain upper			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
alcoholic pancreatitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
gastritis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
haematemesis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
haemorrhoids			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
hiatus hernia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
pancreatitis acute			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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

volvulus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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			
nephrolithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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 colic			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
tubulointerstitial nephritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
urinary retention			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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			
intervertebral disc protrusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
cellulitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
chronic tonsillitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
complicated appendicitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
diverticulitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
osteomyelitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
urinary tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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

vestibular neuronitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
diabetic ketoacidosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (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
hypokalaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo/Galcanezumab - Follow-up Phase	Galcanezumab 120mg/Galcanezumab - Follow-up Phase	Galcanezumab 240mg/Galcanezumab - Follow-up Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 438 (1.14%)	3 / 223 (1.35%)	1 / 228 (0.44%)
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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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 cancer			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung adenocarcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant nipple neoplasm			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tongue neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
uterine leiomyoma			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed[1]	0 / 376 (0.00%)	0 / 186 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
varicose vein			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed[2]	0 / 376 (0.00%)	0 / 186 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
swelling face			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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			

dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epistaxis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemoptysis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	1 / 223 (0.45%)	0 / 228 (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
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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			
foot fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 438 (0.23%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
skin laceration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
congenital diaphragmatic hernia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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			
acute myocardial infarction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
angina unstable			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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 failure congestive			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ventricular extrasystoles			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 438 (0.23%)	0 / 223 (0.00%)	0 / 228 (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			
migraine			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
orthostatic intolerance			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
seizure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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			
abdominal adhesions			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abdominal pain lower			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	1 / 223 (0.45%)	0 / 228 (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
abdominal pain upper			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 438 (0.23%)	0 / 223 (0.00%)	0 / 228 (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
alcoholic pancreatitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematemesis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 438 (0.23%)	0 / 223 (0.00%)	0 / 228 (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
haemorrhoids			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

hiatus hernia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 438 (0.23%)	0 / 223 (0.00%)	0 / 228 (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
pancreatitis acute			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
volvulus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 438 (0.23%)	0 / 223 (0.00%)	0 / 228 (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
urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	1 / 228 (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
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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 colic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tubulointerstitial nephritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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 retention			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 438 (0.23%)	0 / 223 (0.00%)	0 / 228 (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
Musculoskeletal and connective tissue disorders			
intervertebral disc protrusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic tonsillitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
complicated appendicitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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 24.0			

subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteomyelitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	1 / 223 (0.45%)	0 / 228 (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
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vestibular neuronitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic ketoacidosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypokalaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
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	Israel Addendum		
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 29 (20.69%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
colon cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
lung adenocarcinoma			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
malignant nipple neoplasm				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
oesophageal adenocarcinoma				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
squamous cell carcinoma				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tongue neoplasm malignant stage unspecified				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
uterine leiomyoma				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed[1]	1 / 25 (4.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
deep vein thrombosis				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
varicose vein				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
abortion spontaneous				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed[2]	0 / 25 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
non-cardiac chest pain				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
swelling face				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
dyspnoea				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
epistaxis				
alternative dictionary used:				

MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
haemoptysis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pulmonary embolism				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
confusional state				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
foot fracture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
road traffic accident				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
skin laceration				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
congenital diaphragmatic hernia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
acute myocardial infarction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
angina unstable				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cardiac failure congestive				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
myocardial infarction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ventricular extrasystoles				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
migraine			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
orthostatic intolerance			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
seizure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
iron deficiency anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
abdominal adhesions			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
abdominal pain lower			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
abdominal pain upper				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
alcoholic pancreatitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastritis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
haematemesis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
haemorrhoids				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hiatus hernia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

nausea				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pancreatitis acute				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
small intestinal obstruction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
volvulus				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
vomiting				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
cholelithiasis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
rash				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
urticaria				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
nephrolithiasis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
renal colic				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tubulointerstitial nephritis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
urinary retention				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
intervertebral disc protrusion				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
appendicitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cellulitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
chronic tonsillitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
complicated appendicitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diverticulitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
osteomyelitis				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
upper respiratory tract infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
urinary tract infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
vestibular neuronitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
dehydration				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diabetic ketoacidosis				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hypokalaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 29 (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.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: 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	Galcanezumab 120mg - Double-Blind Treatment Phase	Placebo - Double-Blind Treatment Phase	Galcanezumab 240mg - Double-Blind Treatment Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	98 / 273 (35.90%)	170 / 558 (30.47%)	105 / 282 (37.23%)
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 273 (0.73%)	0 / 558 (0.00%)	1 / 282 (0.35%)
occurrences (all)	2	0	2
fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	6 / 273 (2.20%)	6 / 558 (1.08%)	7 / 282 (2.48%)
occurrences (all)	6	6	8
influenza like illness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 273 (1.47%)	3 / 558 (0.54%)	4 / 282 (1.42%)
occurrences (all)	4	3	4
injection site erythema			
alternative dictionary used:			

MedDRA 24.0			
subjects affected / exposed	4 / 273 (1.47%)	5 / 558 (0.90%)	13 / 282 (4.61%)
occurrences (all)	5	5	16
injection site pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	18 / 273 (6.59%)	24 / 558 (4.30%)	21 / 282 (7.45%)
occurrences (all)	31	32	33
injection site reaction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	8 / 273 (2.93%)	10 / 558 (1.79%)	15 / 282 (5.32%)
occurrences (all)	13	16	19
peripheral swelling			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 273 (0.37%)	1 / 558 (0.18%)	1 / 282 (0.35%)
occurrences (all)	1	1	1
pyrexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 273 (1.83%)	1 / 558 (0.18%)	1 / 282 (0.35%)
occurrences (all)	5	1	1
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 273 (1.47%)	3 / 558 (0.54%)	4 / 282 (1.42%)
occurrences (all)	4	3	4
oropharyngeal pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 273 (0.73%)	3 / 558 (0.54%)	4 / 282 (1.42%)
occurrences (all)	2	3	4
pleural effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

sleep disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 273 (0.37%)	1 / 558 (0.18%)	0 / 282 (0.00%)
occurrences (all)	1	1	0
Cardiac disorders			
pericardial effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	6 / 273 (2.20%)	19 / 558 (3.41%)	9 / 282 (3.19%)
occurrences (all)	7	20	10
headache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 273 (1.47%)	8 / 558 (1.43%)	1 / 282 (0.35%)
occurrences (all)	4	9	1
hypoaesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	2 / 558 (0.36%)	1 / 282 (0.35%)
occurrences (all)	0	2	1
tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 273 (0.37%)	0 / 558 (0.00%)	2 / 282 (0.71%)
occurrences (all)	1	0	2
Gastrointestinal disorders			
ascites			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	1 / 282 (0.35%)
occurrences (all)	0	0	1

flatulence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 273 (3.30%)	22 / 558 (3.94%)	8 / 282 (2.84%)
occurrences (all)	12	26	8
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	1 / 558 (0.18%)	1 / 282 (0.35%)
occurrences (all)	0	1	1
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	2 / 558 (0.36%)	1 / 282 (0.35%)
occurrences (all)	0	2	1
urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 273 (0.73%)	3 / 558 (0.54%)	0 / 282 (0.00%)
occurrences (all)	3	3	0
Renal and urinary disorders			
renal cyst			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 273 (0.73%)	8 / 558 (1.43%)	5 / 282 (1.77%)
occurrences (all)	2	8	5
back pain			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	8 / 273 (2.93%)	14 / 558 (2.51%)	2 / 282 (0.71%)
occurrences (all)	9	15	2
neck pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	7 / 273 (2.56%)	7 / 558 (1.25%)	0 / 282 (0.00%)
occurrences (all)	8	7	0
pain in extremity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 273 (1.10%)	5 / 558 (0.90%)	2 / 282 (0.71%)
occurrences (all)	3	5	2
spinal osteoarthritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	1 / 558 (0.18%)	0 / 282 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 273 (1.83%)	3 / 558 (0.54%)	1 / 282 (0.35%)
occurrences (all)	5	3	1
covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 273 (0.73%)	1 / 558 (0.18%)	2 / 282 (0.71%)
occurrences (all)	2	1	2
infectious mononucleosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 273 (0.00%)	15 / 558 (2.69%)	6 / 282 (2.13%)
occurrences (all)	0	16	6
nasopharyngitis alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	18 / 273 (6.59%)	24 / 558 (4.30%)	9 / 282 (3.19%)
occurrences (all)	20	26	9
pancreas infection alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences (all)	0	0	0
pneumonia alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 273 (0.37%)	1 / 558 (0.18%)	2 / 282 (0.71%)
occurrences (all)	1	1	2
sinusitis alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 273 (1.47%)	5 / 558 (0.90%)	7 / 282 (2.48%)
occurrences (all)	4	5	7
upper respiratory tract infection alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	8 / 273 (2.93%)	14 / 558 (2.51%)	9 / 282 (3.19%)
occurrences (all)	10	14	9
urinary tract infection alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	6 / 273 (2.20%)	6 / 558 (1.08%)	5 / 282 (1.77%)
occurrences (all)	6	6	5
Metabolism and nutrition disorders hypercalcaemia alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 273 (0.00%)	0 / 558 (0.00%)	0 / 282 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Galcanezumab 240mg/Galcanezumab - Open-Label Extension Phase	Galcanezumab 120mg/Galcanezumab - Open-Label Extension Phase	Placebo/Galcanezumab - Open-Label Extension Phase
Total subjects affected by non-serious adverse events			

subjects affected / exposed	120 / 262 (45.80%)	117 / 259 (45.17%)	223 / 501 (44.51%)
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 262 (0.76%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences (all)	2	0	1
fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	8 / 262 (3.05%)	1 / 259 (0.39%)	7 / 501 (1.40%)
occurrences (all)	9	1	7
influenza like illness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 262 (0.76%)	2 / 259 (0.77%)	5 / 501 (1.00%)
occurrences (all)	3	2	5
injection site erythema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	10 / 262 (3.82%)	6 / 259 (2.32%)	12 / 501 (2.40%)
occurrences (all)	19	6	18
injection site pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 262 (1.91%)	5 / 259 (1.93%)	8 / 501 (1.60%)
occurrences (all)	6	6	10
injection site reaction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	17 / 262 (6.49%)	21 / 259 (8.11%)	19 / 501 (3.79%)
occurrences (all)	33	56	51
peripheral swelling			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	4 / 501 (0.80%)
occurrences (all)	0	0	6
pyrexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 262 (1.15%)	3 / 259 (1.16%)	5 / 501 (1.00%)
occurrences (all)	4	3	5
Respiratory, thoracic and mediastinal			

disorders			
cough			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 262 (3.44%)	3 / 259 (1.16%)	8 / 501 (1.60%)
occurrences (all)	9	3	9
oropharyngeal pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 262 (1.53%)	5 / 259 (1.93%)	8 / 501 (1.60%)
occurrences (all)	4	5	10
pleural effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
sleep disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
pericardial effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	7 / 262 (2.67%)	4 / 259 (1.54%)	10 / 501 (2.00%)
occurrences (all)	11	5	10
headache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 262 (0.76%)	5 / 259 (1.93%)	7 / 501 (1.40%)
occurrences (all)	3	5	7
hypoaesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	1 / 259 (0.39%)	4 / 501 (0.80%)
occurrences (all)	0	1	4

tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	1 / 259 (0.39%)	2 / 501 (0.40%)
occurrences (all)	0	1	2
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 262 (0.76%)	1 / 259 (0.39%)	5 / 501 (1.00%)
occurrences (all)	2	1	5
Gastrointestinal disorders			
ascites			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	1 / 259 (0.39%)	2 / 501 (0.40%)
occurrences (all)	0	1	2
nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	11 / 262 (4.20%)	4 / 259 (1.54%)	7 / 501 (1.40%)
occurrences (all)	12	5	8
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 262 (0.76%)	4 / 259 (1.54%)	5 / 501 (1.00%)
occurrences (all)	4	4	6
urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 262 (0.38%)	2 / 259 (0.77%)	8 / 501 (1.60%)
occurrences (all)	1	2	11

Renal and urinary disorders			
renal cyst			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	7 / 262 (2.67%)	5 / 259 (1.93%)	25 / 501 (4.99%)
occurrences (all)	9	6	28
back pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	13 / 262 (4.96%)	13 / 259 (5.02%)	11 / 501 (2.20%)
occurrences (all)	13	13	12
neck pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	12 / 262 (4.58%)	6 / 259 (2.32%)	3 / 501 (0.60%)
occurrences (all)	13	6	3
pain in extremity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 262 (1.53%)	2 / 259 (0.77%)	10 / 501 (2.00%)
occurrences (all)	4	2	10
spinal osteoarthritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences (all)	0	0	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	7 / 262 (2.67%)	7 / 259 (2.70%)	14 / 501 (2.79%)
occurrences (all)	8	7	14
covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences (all)	0	0	0

gastroenteritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 262 (0.76%)	7 / 259 (2.70%)	8 / 501 (1.60%)
occurrences (all)	2	7	9
infectious mononucleosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	12 / 262 (4.58%)	17 / 259 (6.56%)	14 / 501 (2.79%)
occurrences (all)	13	21	15
nasopharyngitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	27 / 262 (10.31%)	24 / 259 (9.27%)	45 / 501 (8.98%)
occurrences (all)	32	31	55
pancreas infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 262 (0.38%)	0 / 259 (0.00%)	1 / 501 (0.20%)
occurrences (all)	1	0	1
sinusitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	10 / 262 (3.82%)	5 / 259 (1.93%)	16 / 501 (3.19%)
occurrences (all)	11	7	17
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	18 / 262 (6.87%)	17 / 259 (6.56%)	27 / 501 (5.39%)
occurrences (all)	23	21	31
urinary tract infection			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	5 / 262 (1.91%)	6 / 259 (2.32%)	29 / 501 (5.79%)
occurrences (all)	6	7	33
Metabolism and nutrition disorders			
hypercalcaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 262 (0.00%)	0 / 259 (0.00%)	0 / 501 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo - Follow-up Phase	Galcanezumab 120mg - Follow-up Phase	Galcanezumab 240mg - Follow-up Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	2 / 4 (50.00%)
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
injection site erythema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
peripheral swelling			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pleural effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Psychiatric disorders			
sleep disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
pericardial effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Nervous system disorders			

dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ascites			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
flatulence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			

cholelithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
renal cyst			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

spinal osteoarthritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
infectious mononucleosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
influenza			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pancreas infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
pneumonia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
hypercalcaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Placebo/Galcanezumab - Follow-up Phase	Galcanezumab 120mg/Galcanezumab - Follow-up Phase	Galcanezumab 240mg/Galcanezumab - Follow-up Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	57 / 438 (13.01%)	19 / 223 (8.52%)	27 / 228 (11.84%)
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 438 (0.68%)	0 / 223 (0.00%)	1 / 228 (0.44%)
occurrences (all)	3	0	1
influenza like illness			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	1 / 228 (0.44%)
occurrences (all)	0	0	1
injection site erythema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
peripheral swelling			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 438 (0.68%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	3	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	1 / 223 (0.45%)	1 / 228 (0.44%)
occurrences (all)	0	1	1
pleural effusion			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
sleep disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	1 / 228 (0.44%)
occurrences (all)	0	0	1
Cardiac disorders			
pericardial effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 438 (0.23%)	0 / 223 (0.00%)	2 / 228 (0.88%)
occurrences (all)	2	0	3
headache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 438 (0.23%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	1	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	1 / 228 (0.44%)
occurrences (all)	0	0	1
tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	2 / 228 (0.88%)
occurrences (all)	0	0	2
Gastrointestinal disorders			

ascites			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 438 (0.46%)	1 / 223 (0.45%)	2 / 228 (0.88%)
occurrences (all)	2	1	2
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 438 (0.46%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
pruritus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 438 (0.23%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	1	0	0
urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 438 (0.46%)	0 / 223 (0.00%)	1 / 228 (0.44%)
occurrences (all)	2	0	2
Renal and urinary disorders			
renal cyst			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	7 / 438 (1.60%)	1 / 223 (0.45%)	0 / 228 (0.00%)
occurrences (all)	7	1	0
back pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 438 (0.46%)	4 / 223 (1.79%)	0 / 228 (0.00%)
occurrences (all)	2	4	0
neck pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 438 (1.14%)	1 / 223 (0.45%)	1 / 228 (0.44%)
occurrences (all)	5	1	1
pain in extremity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 438 (0.46%)	0 / 223 (0.00%)	3 / 228 (1.32%)
occurrences (all)	2	0	3
spinal osteoarthritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 438 (0.46%)	2 / 223 (0.90%)	3 / 228 (1.32%)
occurrences (all)	2	2	3
covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 438 (0.46%)	1 / 223 (0.45%)	1 / 228 (0.44%)
occurrences (all)	2	1	1
infectious mononucleosis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 438 (1.14%)	2 / 223 (0.90%)	4 / 228 (1.75%)
occurrences (all)	5	2	4
nasopharyngitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	11 / 438 (2.51%)	2 / 223 (0.90%)	1 / 228 (0.44%)
occurrences (all)	11	2	3
pancreas infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	7 / 438 (1.60%)	1 / 223 (0.45%)	1 / 228 (0.44%)
occurrences (all)	7	2	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 438 (0.91%)	2 / 223 (0.90%)	3 / 228 (1.32%)
occurrences (all)	4	2	3
urinary tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 438 (2.05%)	3 / 223 (1.35%)	3 / 228 (1.32%)
occurrences (all)	10	3	3
Metabolism and nutrition disorders			
hypercalcaemia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 438 (0.00%)	0 / 223 (0.00%)	0 / 228 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Israel Addendum		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 29 (89.66%)		
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		
fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 29 (13.79%)		
occurrences (all)	4		
influenza like illness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 29 (13.79%)		
occurrences (all)	7		
injection site erythema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 29 (10.34%)		
occurrences (all)	4		
injection site pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 29 (10.34%)		
occurrences (all)	3		
injection site reaction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 29 (10.34%)		
occurrences (all)	4		
peripheral swelling			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		

pyrexia alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all)	 2 / 29 (6.90%) 2		
Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all) oropharyngeal pain alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all) pleural effusion alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all)	 2 / 29 (6.90%) 2 6 / 29 (20.69%) 7 0 / 29 (0.00%) 0		
Psychiatric disorders sleep disorder alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all)	 4 / 29 (13.79%) 4		
Cardiac disorders pericardial effusion alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all)	 0 / 29 (0.00%) 0		
Nervous system disorders dizziness alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all) headache alternative dictionary used: MedDRA 24.0	 3 / 29 (10.34%) 4 		

subjects affected / exposed	3 / 29 (10.34%)		
occurrences (all)	4		
hypoaesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		
Gastrointestinal disorders			
ascites			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
flatulence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 29 (13.79%)		
occurrences (all)	4		
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			

pruritus alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all)	4 / 29 (13.79%) 4		
urticaria alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all)	3 / 29 (10.34%) 3		
Renal and urinary disorders renal cyst alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all)	2 / 29 (6.90%) 4		
back pain alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all)	3 / 29 (10.34%) 4		
neck pain alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all)	3 / 29 (10.34%) 3		
pain in extremity alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all)	3 / 29 (10.34%) 3		
spinal osteoarthritis alternative dictionary used: MedDRA 24.0 subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Infections and infestations			

bronchitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 29 (10.34%)			
occurrences (all)	3			
covid-19				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 29 (6.90%)			
occurrences (all)	2			
gastroenteritis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 29 (6.90%)			
occurrences (all)	2			
infectious mononucleosis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences (all)	1			
influenza				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences (all)	0			
nasopharyngitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	5 / 29 (17.24%)			
occurrences (all)	6			
pancreas infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences (all)	0			
pneumonia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 29 (6.90%)			
occurrences (all)	3			
sinusitis				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		
upper respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		
urinary tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 29 (13.79%)		
occurrences (all)	4		
Metabolism and nutrition disorders			
hypercalcaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 January 2016	-Study Design: Added language regarding the contents of each injection for the different treatment assignments in order to clarify how treatment is blinded. -Exclusion criteria: Excluded patients with a prior lifetime history of stroke to provide additional safeguards for patients who may be at risk for stroke. -Safety Monitoring: Added text to indicate that additional neurological examinations will be conducted to assess for possible cerebrovascular events, along with instructions for appropriate follow-up. - Blinding: Revised wording regarding procedures associated with emergency unblinding such that investigators no longer need to contact Lilly prior to emergency unblinding of a patient's treatment assignment. - Concomitant therapy: Added the list of allowed and disallowed concomitant treatments. - Permanent Discontinuation from Study Treatment: Modified treatment discontinuation criteria to require (rather than recommend) discontinuation of treatment in the event of specific liver function test abnormalities, and added language to indicate the additional events requiring discontinuation from LY2951742 or placebo. - Determination of Sample size: Added assumptions of minimal sample size calculation; Added information regarding the approximate number of countries, investigative sites, and patients planned for inclusion in the study. - Key secondary analysis: Provided additional details regarding statistical control of the familywise type 1 error rate for the primary and key secondary endpoints. - Immunogenicity Analysis: Added clarification on the statistical model to be used for subgroup analyses.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported