Clinical trial results:
Assessment of Prolonged safety and tOLerability of erenumab in migraine patients in a Long-term OpeN-label study (APOLLON)

Summary

EudraCT number	2019-002201-22
Trial protocol	DE
Global end of trial date	13 March 2023

Results information

Result version number	v1 (current)
This version publication date	26 January 2024
First version publication date	26 January 2024

Trial information

Trial identification

Sponsor protocol code	CAMG334ADE03

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04084314
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Novartis campus, Basel, Switzerland, CH-4056
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@novartis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 March 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 March 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the trial was to evaluate the long-term safety of 70 and 140 mg erenumab in patients with episodic migraine or chronic migraine.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 September 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 701
Worldwide total number of subjects	701
EEA total number of subjects	701

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	695
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in 79 investigative sites in Germany.

Pre-assignment

Screening details:

The screening period began once patients had signed the study informed consent. The Screening Epoch had a duration of 2 weeks. Eligible patients came from study CAMG334ADE01 (NCT03828539).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Erenumab

Arm description:

Erenumab dose could be adjusted from 70 mg to 140 mg or vice versa at the discretion of the physician at any scheduled study visit.

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

Dosage and administration details:

Erenumab dose could be adjusted from 70 mg to 140 mg or vice versa at the discretion of the physician at any scheduled study visit. Erenumab was supplied in pre-filled autoinjectors containing 70 mg or 140 mg erenumab. Study treatment was administered by subcutaneous injection every 4 weeks.
The planned duration of treatment was 128 weeks for individual patients. However, each patient was eligible to one voluntary treatment interruption of up to 24 weeks (approximately 6 months) after an initial treatment duration of at least 12 weeks. After such a voluntary treatment interruption within the 128 weeks of the Treatment Epoch patients could return to the treatment schedule.

Number of subjects in period 1	Erenumab
Started	701
Completed	534
Not completed	167
Physician decision	4
Adverse Event	24
Protocol Deviation	3
Pregnancy	9
Lost to follow-up	19
Withdrawal of informed consent	8
Subject/guardian decision	91

New therapy for study indication	9

Baseline characteristics

Reporting groups	
Reporting group title	Erenumab
Reporting group description:	
Erenumab dose could be adjusted from 70 mg to 140 mg or vice versa at the discretion of the physician at any scheduled study visit.	

Reporting group values	Erenumab	Total	
Number of subjects	701	701	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	695	695	
From 65-84 years	6	6	
85 years and over	0	0	
Age Continuous Units: years			
arithmetic mean	41.8		
standard deviation	± 12.3	-	
Sex: Female, Male Units: participants			
Female	608	608	
Male	93	93	
Race/Ethnicity, Customized Units: Subjects			
White	695	695	
Asian	1	1	
Unknown	1	1	
Other	4	4	

End points

End points reporting groups

Reporting group title	Erenumab

Reporting group description:

Erenumab dose could be adjusted from 70 mg to 140 mg or vice versa at the discretion of the physician at any scheduled study visit.

Primary: Exposure adjusted incidence rate of AE during Open-label Treatment Epoch per 100 subject years

End point title	Exposure adjusted incidence rate of AE during Open-label Treatment Epoch per 100 subject years[1]

End point description:

This outcome measure was calculated dividing the number of adverse events (AEs) by the total patient exposure time and standardizing it per 100 patient-years. Exact Pearson-Clopper confidence intervals for single proportions were calculated to evaluate the precision of the estimated parameter.

End point type	Primary

End point timeframe:

Up to 128 weeks

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis were planned for this endpoint.

End point values	Erenumab			
Subject group type	Reporting group			
Number of subjects analysed	701			
Units: number of AEs per 100 patient-years				
number (confidence interval 95%)	101.71 (92.28 to 111.14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of patients discontinuing Open-label Treatment Epoch due to non-AE reasons

End point title	Proportion of patients discontinuing Open-label Treatment Epoch due to non-AE reasons

End point description:

Participants discontinuing the Open-label Treatment Epoch due to non-AE reasons to evaluate the long-term tolerability of erenumab in patients with episodic migraine or chronic migraine.

End point type	Secondary

End point timeframe:

Up to 128 weeks

End point values	Erenumab			
Subject group type	Reporting group			
Number of subjects analysed	701			
Units: Participants	126			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of patients discontinuing Open-label Treatment Epoch due to AE

End point title	Proportion of patients discontinuing Open-label Treatment Epoch due to AE

End point description:

Participants discontinuing the Open-label Treatment Epoch due to adverse events (AEs) to evaluate the long-term tolerability of erenumab in patients with episodic migraine or chronic migraine.

End point type	Secondary

End point timeframe:

Up to 128 weeks

End point values	Erenumab			
Subject group type	Reporting group			
Number of subjects analysed	701			
Units: Participants	29			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study treatment in the Open-label Treatment Epoch of this study to 8 weeks after last dose (up to 132 weeks).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Erenumab

Reporting group description:

Erenumab dose could be adjusted from 70 mg to 140 mg or vice versa at the discretion of the physician at any scheduled study visit.

Serious adverse events	Erenumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	86 / 701 (12.27%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholangiocarcinoma			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast cancer			
subjects affected / exposed	2 / 701 (0.29%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Raynaud's phenomenon			

subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Circulatory collapse				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
Retroplacental haematoma				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ectopic pregnancy				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abortion spontaneous				
subjects affected / exposed	2 / 701 (0.29%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Capsular contracture associated with breast implant				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pain				

subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Uterine prolapse			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endometriosis			
subjects affected / exposed	2 / 701 (0.29%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vaginal haemorrhage			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Ovarian cyst			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Depression			
subjects affected / exposed	5 / 701 (0.71%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	2 / 701 (0.29%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Panic attack			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Major depression			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Depression suicidal			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Arthropod sting			
subjects affected / exposed	2 / 701 (0.29%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bursa injury			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Contusion				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epicondylitis				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ligament rupture				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Muscle rupture				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural haematoma				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post-traumatic neck syndrome				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Road traffic accident				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Shoulder fracture				

subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Macrocornea			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	2 / 701 (0.29%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nerve compression			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Multiple sclerosis			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Migraine			
subjects affected / exposed	2 / 701 (0.29%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypoaesthesia			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrospinal fluid leakage			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cerebellar atrophy			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vestibular paroxysmia			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	2 / 701 (0.29%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Eye disorders			

Lens dislocation				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cataract				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain lower				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Volvulus				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestine polyp				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal stenosis				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Internal hernia				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Eosinophilic oesophagitis				

subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enteritis			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal fistula			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Large intestinal stenosis			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	2 / 701 (0.29%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Ureterolithiasis			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Renal colic				
subjects affected / exposed	2 / 701 (0.29%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Goitre				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Back pain				
subjects affected / exposed	4 / 701 (0.57%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Bursitis				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cervical spinal stenosis				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	7 / 701 (1.00%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Osteitis				
subjects affected / exposed	1 / 701 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Osteoarthritis			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rotator cuff syndrome			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Sacral pain			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Synovitis			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tendonitis			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vertebral osteophyte			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	4 / 701 (0.57%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Appendicitis perforated			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bartholinitis			

subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal viral infection			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nephritis bacterial			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Root canal infection			

subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vestibular neuronitis			
subjects affected / exposed	1 / 701 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Erenumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	514 / 701 (73.32%)		
Injury, poisoning and procedural complications			
Post vaccination fever			
subjects affected / exposed	15 / 701 (2.14%)		
occurrences (all)	17		
Immunisation reaction			
subjects affected / exposed	43 / 701 (6.13%)		
occurrences (all)	53		
Procedural pain			
subjects affected / exposed	16 / 701 (2.28%)		
occurrences (all)	18		
Vascular disorders			
Hypertension			

subjects affected / exposed occurrences (all)	46 / 701 (6.56%) 46		
Nervous system disorders Migraine subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Dizziness subjects affected / exposed occurrences (all)	 43 / 701 (6.13%) 53 42 / 701 (5.99%) 48 24 / 701 (3.42%) 29		
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Chills subjects affected / exposed occurrences (all)	 20 / 701 (2.85%) 24 61 / 701 (8.70%) 74 20 / 701 (2.85%) 23		
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	 25 / 701 (3.57%) 26		
Gastrointestinal disorders Abdominal pain upper subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all)	 15 / 701 (2.14%) 15 34 / 701 (4.85%) 38 17 / 701 (2.43%) 21		

Constipation			
subjects affected / exposed	103 / 701 (14.69%)		
occurrences (all)	124		
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	20 / 701 (2.85%)		
occurrences (all)	24		
Cough			
subjects affected / exposed	18 / 701 (2.57%)		
occurrences (all)	19		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	28 / 701 (3.99%)		
occurrences (all)	32		
Pruritus			
subjects affected / exposed	18 / 701 (2.57%)		
occurrences (all)	33		
Psychiatric disorders			
Depression			
subjects affected / exposed	39 / 701 (5.56%)		
occurrences (all)	40		
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	29 / 701 (4.14%)		
occurrences (all)	36		
Osteoarthritis			
subjects affected / exposed	17 / 701 (2.43%)		
occurrences (all)	17		
Muscle spasms			
subjects affected / exposed	15 / 701 (2.14%)		
occurrences (all)	15		
Back pain			
subjects affected / exposed	42 / 701 (5.99%)		
occurrences (all)	43		
Arthralgia			

subjects affected / exposed	33 / 701 (4.71%)		
occurrences (all)	36		
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	18 / 701 (2.57%)		
occurrences (all)	24		
Tonsillitis			
subjects affected / exposed	18 / 701 (2.57%)		
occurrences (all)	22		
Nasopharyngitis			
subjects affected / exposed	134 / 701 (19.12%)		
occurrences (all)	173		
Cystitis			
subjects affected / exposed	23 / 701 (3.28%)		
occurrences (all)	37		
COVID-19			
subjects affected / exposed	242 / 701 (34.52%)		
occurrences (all)	261		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 April 2020	Inclusion of patients with chronic migraine and restriction of transition from the trial CAMG334ADE01 to 3 months.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported