Study of Efficacy and Safety of AMG 334 in Adult Episodic Migraine Patients

14/11/2024 08:31:21

Main Information

Primary registry identifying number
LBCTR2019060240

Protocol number
AMG334A2302

MOH registration number
49904/2017

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Retrospective

Type of registration: Justify
LCTR was recently initiated, original file was previously submitted by Paper

Date of registration in national regulatory agency
20/12/2017

Primary sponsor
Novartis Pharma Services Inc.

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
17/12/2019

Date of registration in national regulatory agency
20/12/2017

Public title
Study of Efficacy and Safety of AMG 334 in Adult Episodic Migraine Patients

Acronym
EMPOWER

Scientific title
A 12-week Double-blind, Randomized, Multi-center Study Comparing the Efficacy and Safety of Once Monthly Subcutaneous AMG 334 Against Placebo in Adult Episodic Migraine Patients (EMPOwER)

Acronym

Brief summary of the study: English
The purpose of this study is to evaluate the efficacy and safety of AMG334 in countries beyond the United States (US) and European Union (EU).

Brief summary of the study: Arabic
أسبوعًا تقارن ما بين فعاليّة وسلامة جرعة شهريّة واحدة تحت الجلد من دواء12دراسة متعددة المراكز، عشوائية التوزيع، مزدوجة التعمية من AMG 334 مقابل الدواء الوهمي لدى مرضى بالغين مصابين بالصداع النصفي العرضي (EMPOwER)

Health conditions/problem studied: Specify
Migraine

Interventions: Specify
•Biological: Erenumab
AMG334 is a fully human monoclonal antibody targeting the CGRP receptor under development for migraine prophylaxis in adults.

•Other: Placebo
Placebo will match the active study drug and will be administered similarly.

Key inclusion and exclusion criteria: Inclusion criteria
1.Documented history of migraine in the 12 months prior to screening
2.4-14 days per month of migraine symptoms

3.>=80% diary compliance during the Baseline period

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

65

Key inclusion and exclusion criteria: Exclusion criteria

1.>50 years old at migraine onset
2.Pregnant or nursing
3.History of cluster or hemiplegic headache
4.Evidence of seizure or major psychiatric disorder
5.Score of 19 or higher on the BDI
6.Active chronic pain syndrome
7.Cardiac or hepatic disease

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Other

Trial scope: Specify scope

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Placebo

Study phase

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Worldwide

IMP has market authorization: Specify

USA, Europe (Austria, Croatia, Czec republic, Denmark, Estonia, Finland, Germany, Iceland, Italy, Latvia, Poland, Portugal, Norway, Sweden, Switzerland, UK)

Name of IMP

erenumab (AIMOVIG)

Year of authorization

Month of authorization

Type of IMP

Others

Pharmaceutical class

Erenumab (Aimovig) is a human monoclonal immunoglobulin G2 (IgG2) that is directed against the canonical CGRP receptor, where it inhibits and blocks the action of CGRP.

Therapeutic indication

Preventive treatment of migraine in adults.

Therapeutic benefit

The primary efficacy endpoint was 50% reduction in MMD while change from baseline in MMD was a secondary endpoint, also showed positive outcomes. Considering the totality of data, erenumab 70 mg has shown robust and consistent clinically and statistically significant efficacy with no significant dose-dependent adverse events, while erenumab 140 mg has shown even greater treatment effects along with a favorable safety and tolerability profile that was similar to erenumab 70 mg.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples with DNA**

Biospecimen description

A central laboratory will be used for analysis of all specimens collected.
Quintiles Ltd. – Scotland; Q² Solutions; The Alba Campus; Rosebank; Livingston; West Lothian; EH54 7EG; United Kingdom; Telephone: 01506816043
Hematology: red blood cells (RBCs), nucleated RBCs, hemoglobin, hematocrit, MCV, MCH, MCHC, RDW, reticulocytes, platelets, white blood cells (WBCs), WBC differential. The differential will measure: bands/stabs, neutrophils, eosinophils, basophils, lymphocytes, monocytes, myeloblasts, promyelocytes, myelocytes, metamyelocytes, and atypical lymphocytes.
Chemistry: sodium, potassium, chloride, bicarbonate, total protein, albumin, calcium, magnesium, phosphorus, glucose, BUN/urea, bilirubin (direct and total), alkaline phosphatase, ALT (SGPT), AST (SGOT), total cholesterol, HDL, LDL, triglycerides, CPK, and eGFR.
Urinalysis: specific gravity, pH, blood, protein, glucose, bilirubin, WBC, RBC, epithelial cells, bacteria, casts, and crystals

Target sample size

49

Actual enrollment target size

49

Date of first enrollment: Type

Actual

Date of first enrollment: Date

08/02/2018

Date of study closure: Type

Actual

Date of study closure: Date

07/02/2020

Recruitment status

Complete

Recruitment status: Specify

Date of completion

31/05/2019

IPD sharing statement plan

Yes

IPD sharing statement description

Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com

Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT03333109

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinicaltrials.gov	NCT03333109

Sources of Monetary or Material Support

Name
Novartis Pharma Services Inc.

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Taghrid Hajj	Beirut	Lebanon	03/494008	taghridelhajj@gmail.com	Rafik Hariri University Hospital
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Public	Achraf Makki	Beirut	Lebanon	70/878886	am132@aub.edu.lb	American University Of Beirut Medical Center
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Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Rafic Hariri University Hospital	Dr. Taghrid Hajj	Neurologist	Approved
American University of Beirut Medical Center	Dr. Achraf Makki	Neurologist	Approved
Bellevue Medical Center	Dr. Ghassan Mehanna	Neurologist	Approved
Ain Wazein Medical Village	Dr. Shawkat Beayni	Neurologist	Approved
Makassed General Hospital	Dr. Salim Atrouni	Neurologist	Approved
Lebanese American University Medical Center Rizk Hospital	Dr. Naji Riachi	Neurologist	Approved
Saint George Hospital University Medical Center	Dr Aline Mourad	Neurologist	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	14/06/2018	Fouad Ziyadeh	fz05@aub.edu.lb	+961 (0) 1 350 000 ext:5445
Saint George Hospital University Medical Center	21/06/2018	Michel Daher	mndaher@stgeorgehospital.org	+961 (0)1 441 733
Bellevue Medical Center	25/10/2017	Ghassan Maalouf	gmaalouf@bmc.com.lb	+961 (0) 1 682666 ext 7600
Ain w Zein Medical Village	23/12/2017	Khaled Abdel Baki	Khaled.abdelbaki@awmedicalvillage.org	+961 (0) 5 509 001 ext 2000
Makassed General Hospital	09/11/2017	Mariam Rajab	research.makassed@hotmail.com	01636941
Lebanese American University- University Medical Center Rizk Hospital	24/01/2018	Christine Chalhoub	christine.chalhoub@lau.edu.lb	+961 9 547254 ext. 2340
Rafic Hariri University Hospital	29/11/2017	Rawan Yamout	rawan.yamout@crurhuh.com	018300000 ext 2036

Countries of Recruitment

Name
Lebanon
Argentina
India
Republic of Korea
Malaysia
Mexico
Philippines
Singapore
Taiwan
Thailand
Viet Nam

Health Conditions or Problems Studied

Condition	Code	Keyword
Migraine	Migraine (G43)	Migraine

Interventions

Intervention	Description	Keyword
ICF, Physical Exam, ECG, local Labs	ICF, Physical Exam, ECG, local Labs	ICF, Physical Exam, ECG, local Labs

Primary Outcomes

Name	Time Points	Measure
Change from baseline in monthly migraine days at the last month	3 months	3 months

Key Secondary Outcomes

Name	Time Points	Measure
•Achievement of at least a 50% reduction from baseline in monthly migraine days	3 months	3 months
•Change from Baseline in acute migraine-specific medication treatment days	3 months	3 months
•Change from Baseline in headache impact scores as measured by the HIT-6	3 months	3 months

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files