A Long-Term, Prospective, Observational Study to Evaluate the Safety, Including Cardiovascular Safety, of Fremanezumab in Patients with Migraine in Routine Clinical Practice Non-Interventional Phase 4 Study

First published: 19/04/2020

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42426

EU PAS number

EUPAS34763

Study ID

42426

DARWIN EU® study

No

Study countries

☐ United States

Study description

The study will investigate the incidence of adverse events in a real world setting in migraine patients with long-term exposure to fremanezumab relative to migraine patients treated with other preventive migraine pharmacotherapy targeting the CGRP pathway or other preventive migraine pharmacotherapy not targeting the CGRP pathway. The objective of the study are to evaluate the long-term safety of fremanezumab in all patients with migraine through evaluation of incidence of all adverse events, and to evaluate the safety of fremanezumab in a sub population of CV compromised patients. The secondary objective is to examine the long-term safety of fremanezumab in patients with migraine by migraine treatment duration. This is a long-term, prospective, comparative, non-interventional, observational, controlled study. Patients aged 18 years or older with migraine who have been newly prescribed fremanezumab, non fremanezumab CGRP-pathway targeting preventive migraine medications or non-CGRP-pathway targeting preventive migraine medications will be identified and followed for a minimum of 3 years. Study variables include exposure to the study medications, incidence of adverse events, CV events and MACE (in CV-compromised patients), demographic data, baseline characteristics, medical history, prior use of medications for chronic medical conditions, concomitant medications used for at least 12 months prior to cohort entry, preventative migraine medications, pregnancy status, CV disease, hypertension, and other chronic medical conditions. Exposure to fremanezumab or other preventive migraine medications, medical history (including medicinal products prescribed), comorbidities, primary and secondary outcomes, potential confounding factors, and potential effect modifiers will be documented by the treating physicians.

Study status

Ongoing

Research institutions and networks

Institutions

Syneos Health

United Kingdom

First published: 23/04/2015

Last updated: 06/03/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

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Contact details

Study institution contact

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Study contact

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Primary lead investigator

Natan Kahan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/05/2020

Actual: 01/05/2020

Study start date

Planned: 01/09/2020

Actual: 01/09/2020

Date of final study report

Planned: 01/09/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva Branded Pharmaceutical Products R&D, Inc

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To evaluate the long-term safety of fremanezumab in all patients with migraine and to evaluate the safety of fremanezumab in cardiovascular compromised patients with migraine with regard to cardiovascular events.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

AJOVY

Medical condition to be studied

Migraine

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

6000

Study design details

Outcomes

All adverse events

Data analysis plan

The primary analysis will focus on the comparison of the incidence of all adverse events in patients currently exposed to fremanezumab (Cohort 1), non fremanezumab CGRP-pathway targeting preventive migraine medications (Cohort 2), or non CGRP-pathway targeting preventive migraine medications (Cohort 3). Summary statistics for the incidence of adverse events in patients

with migraine, the sub-population of CV compromised patients with major CV disease or hypertension, and the incidence of adverse events by treatment duration will be reported for each cohort. In addition, summary statistics will be provided by migraine treatment duration, and for CV compromised patients by their CV disease/hypertension status (current or history), for each cohort. Rates for adverse events per person-year of observation will be calculated by cohort. Unadjusted difference of incidence rates with 95% CIs of all adverse events between the treatment cohorts will also be calculated.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No