A Post-marketing Safety Study to Investigate the Risk of Serious CV Events among Galcanezumab (Emgality®) Users Using the Japan Medical Data Center Claim Database (I5Q-JE-B007)

First published: 11/04/2023

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Study Planned

Administrative details

EU PAS number

EUPAS104412

Study ID

104467

DARWIN EU® study

No

Study countries

Japan

Study description

The primary objective of this study is to describe the incidence rate of serious CV events among migraine patients treated with galcanezumab. This objective is descriptive and aims to describe the incidence and distribution of time to first serious CV events in adult patients treated with galcanezumab, overall, by age, gender, and treatment duration of galcanezumab.

Study status

Planned

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Machiko Minatoya

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 25/04/2023

Study start date
Planned: 01/04/2020

Date of final study report
Planned: 30/09/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly Japan K.K

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective of this study is to describe the incidence rate of serious CV events among migraine patients treated with galcanezumab. This objective is descriptive and aims to describe the incidence and distribution of time to first serious CV events in adult patients treated with galcanezumab, overall, by age, gender, and treatment duration of galcanezumab.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02CD02) galcanezumab

galcanezumab

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

6599

Study design details

Outcomes

Serious CV events

Data analysis plan

Calculate the descriptive statistics of the patient characteristics at baseline among galcanezumab group. The incidence and distribution of time to serious CV events among migraine patients treated with galcanezumab, overall, by age, and gender will be described. Incidence of serious CV events of the special populations of interest including with CV events during 12 months prior to initiation of galcanezumab will be calculated. Subgroup analysis for duration of the galcanetumab treatment (e.g. ?18 mo) will be conducted to investigate incidence of serious CV events of galcanetumab users with long-term exposure. Time-to-event analysis using the Kaplan-Meier method will be performed. The patient will be either to have a event or censored at the end of follow-up period.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

JMDC Japan

Data sources (types)

Administrative healthcare records (e.g., claims)

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