

# A Long-Term Observational, Retrospective Cohort Study to Evaluate the Safety, Including Cardiovascular Safety, of Fremanezumab in Patients with Migraine in Routine Clinical Practice in the United States and Europe

**First published:** 06/01/2023

**Last updated:** 16/04/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS50402

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### Study ID

50403

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### DARWIN EU® study

No

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## Study countries

☐ Germany

☐ United States

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## 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.

The objectives of the study are to evaluate: the long-term safety of fremanezumab in patients with migraine, the safety of fremanezumab in a sub population of CV compromised patients and the incidence of new-onset hypertension and worsening of preexisting hypertension in fremanzumab treated patients. This is a retrospective, comparative, controlled, claims and EHR database study. The study population consists of patients with a diagnosis of migraine whose data were recorded in claims databases (Germany) and an EHR database linked to claims (US). The study period will be defined from 3 years before the country-specific launch date of fremanezumab to the most recent data available in each database at the end of 2026. Patients will be enrolled in the study from the country-specific launch date of fremanezumab until 12 months before the most recent data available at the end of 2026 to allow at least 12 months of follow-up for the patients. The long-term use will be investigated in patients with persistent treatment of the drug of interest for at least 3 years with at least 80% adherence. Demographic and medical information, comorbidities, and concomitant medications during the pre-index period will be examined. Use of medications for the preventive treatment of migraine, CV disease, hypertension, and other chronic medical conditions will be collected. Comparisons of the proportions of AEs in fremanezumab and comparative cohorts will be evaluated through a multivariable model with propensity scores used as inverse probability of treatment weighting. The incidence rate ratios of patients observed with worsening of hypertension or

with a new documentation of a diagnostic code for hypertension post index date will be calculated for all cohorts.

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## Study status

Planned

## Research institutions and networks

### Institutions

Clinical, Regulatory and Safety, Cerner Enviza

☐ Germany

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**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

### 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: 31/03/2023

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## **Study start date**

Planned: 29/03/2024

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## **Data analysis start date**

Planned: 01/01/2025

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## **Date of interim report, if expected**

Planned: 27/06/2025

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## **Date of final study report**

Planned: 31/12/2027

# 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

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## 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

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

#### **Main study objective:**

The objectives of the study are to evaluate: the long-term safety of fremanezumab in patients with migraine, the safety of fremanezumab in a sub population of CV compromised patients and the incidence of new-onset hypertension and worsening of preexisting hypertension in fremanzumab treated patients. T

## Study Design

#### **Non-interventional study design**

Cohort

## Study drug and medical condition

## **Study drug International non-proprietary name (INN) or common name**

FREMANEZUMAB

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### **Medical condition to be studied**

Migraine prophylaxis

## 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)

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### **Estimated number of subjects**

5000

## Study design details

### **Outcomes**

incidence of new-onset hypertension and worsening of preexisting hypertension, Hypersensitivity reactions, Alopecia, Anaphylaxis, Angioedema, Constipation, Raynaud's Phenomenon, MI, Stroke, Unstable angina, • To assess the treatment pattern in the fremanezumab and comparative cohorts (i.e. switches from/to treatment, add-on treatments, treatment duration).

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## Data analysis plan

All variables will be analyzed descriptively with appropriate statistical methods: categorical variables by frequency tables (absolute and relative frequencies) and continuous variables by sample statistics (i.e. mean, standard deviation, minimum, median, quartiles and maximum). Comparison of the proportion of AEs between fremanezumab and comparative cohorts will be evaluated through a multivariable model for count data (eg, Poisson or Negative Binomial regression model) with propensity scores used as inverse probability of treatment weighting. For all primary objectives, fremanezumab cohort will be compared to all comparative cohorts. In addition to the comparison of all the patients in the cohorts, the analyses will also be conducted using the subgroups of patients with a long-term use of the drug of interest. The long-term use subgroup will be defined as patients with persistent treatment of the drug of interest for at least 3 years with at least 80% adherence.

## 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 sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

## Use of a Common Data Model (CDM)

**CDM mapping**

No

Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

No