

# 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

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

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS34763

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### Study ID

42426

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### DARWIN EU® study

No

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### Study countries

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 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.

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## **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**

[natan.kahan@teva.co.il](mailto:natan.kahan@teva.co.il)

### Primary lead investigator

Natan Kahan

## Study timelines

### **Date when funding contract was signed**

Planned: 01/05/2020

Actual: 01/05/2020

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### **Study start date**

Planned: 01/09/2020

Actual: 01/09/2020

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### **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

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

EU RMP category 3 (required)

## Methodological aspects

**Study type:**

Non-interventional study

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**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

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**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)

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### **Estimated number of subjects**

6000

## Study design details

### **Outcomes**

All adverse events

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### **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

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### **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

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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