Assessment of pregnancy outcomes in patients treated with Ajovy (fremanezumab): pregnancy registry (Teva migraine pregnancy registry)

First published: 07/12/2020

Last updated: 11/03/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS38442

Study ID

40047

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions and networks

Institutions

Syneos Health

United Kingdom

First published: 23/04/2015

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

Sigal.kaplan@teva.co.il

Primary lead investigator

Sigal Kaplan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/09/2020

Study start date

Planned: 31/12/2020

Actual: 16/12/2020

Date of final study report
Planned: 31/12/2028

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:

Safety study (incl. comparative)

Main study objective:

to assess major adverse maternal, fetal, and infant outcomes during pregnancy and up to 1 year after birth, comparing women exposed to AJOVY (fremanezumab) before or during pregnancy to comparison groups unexposed to AJOVY

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

AJOVY

Medical condition to be studied

Migraine

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Adults (18 to < 46 years)

Estimated number of subjects

1000

Study design details

Outcomes

major congenital anomalies, minor congenital malformations, pregnancy complications, including preeclampsia and eclampsia, pregnancy outcomes, including spontaneous abortions, elective terminations, stillbirths, preterm births, small-for-gestational-age birth (intrauterine growth retardation), and low birth weight (<2500 g), and other adverse outcomes, including postnatal growth and development abnormalities.

Data analysis plan

Descriptive statistics will be provided for the primary endpoint, major congenital malformation rates as well as secondary endpoints of interest, including number, percentage, and 95% confidence intervals (CIs).

Rates of adjudicated major congenital malformations on prospectively enrolled patients will be provided.

The main analyses will be inferential to compare the rates of major congenital malformations between the AJOVY group and each of the 2 internal comparison groups, using a generalized linear model and adjusted for exposure time category (first trimester, second trimester, and third trimester, as appropriate), maternal age group (18 to 39 years, and ≥40 years), and migraine type

(episodic and chronic migraine).

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)

Other

Data sources (types), other

Exposure registry

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