An Open-Label, Single-Dose Study to Assess the Pharmacokinetics and Target Engagement in Cerebral Spinal Fluid and Plasma Following a Single Intravenous Dose of Fremanezumab 900 mg in Healthy Subjects

First published: 13/02/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS103511

Study ID

104846

DARWIN EU® study

No

Study countries

United States

Study description

The goal of this study is to characterize the pharmacokinetics and target engagement of fremanezumab within cerebrospinal fluid (CSF) and plasma after single intravenous administration of a 900 mg dose of fremanezumab. The secondary objective is to evaluate the safety and tolerability of fremanezumab administered iv over a 1 hour infusion, and the exploratory objective is to characterize the relationship between fremanezumab exposure in plasma and CSF and fremanezumab-bound CGRP, inferring the effect of free CGRP. This study will be performed in healthy volunteers at a single site. Inclusion criteria includes being male or non-pregnant female ages 18-60 with no medical concerns, key exclusion criteria includes abnormalities in or around the spinal area, coagulation abnormailities, or use of a CGRP monoclonal antibody in the past 6 months. Study completion is expected April 2023. Qualified researchers may request access to patient level data and related study documents including the study protocol and the statistical analysis plan. Requests will be reviewed for scientific merit, product approval status, and conflicts of interest. Patient level data will be de-identified and study documents will be redacted to protect the privacy of trial participants and to protect commercially confidential information. Please visit www.clinicalstudydatarequest.com to make your request.

Study status

Ongoing

Research institutions and networks

Institutions

Juline Bryson

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Juline Bryson

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/02/2023

Actual: 10/02/2023

Study start date

Planned: 15/02/2023

Actual: 15/02/2023

Date of final study report

Planned: 09/11/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva Pharmaceuticals

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

TV48125-PK-10183

Methodological aspects

Study type

Study type list

Study type:

Clinical trial

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Pharmcakinetics/ Pharmacodynamics

Main study objective:

To characterize the pharmacokinetics and target engagement of fremanezumab within cerebrospinal fluid (CSF) and plasma after single intravenous administration of a 900 mg dose of fremanezumab.

Study drug and medical condition

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

FREMANEZUMAB

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

25

Study design details

Outcomes

To characterize the pharmacokinetics and target engagement of fremanezumab within cerebrospinal fluid (CSF) and plasma after single intravenous administration of a 900 mg dose of fremanezumab. To evaluate the safety and tolerability of fremanezumab administered iv over a 1 hour infusion

Data analysis plan

Descriptive statistics (n, mean, standard deviation, standard error of mean, median, minimum, and maximum) will be provided for actual values

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

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