A Randomized, Placebo-Controlled, Parallel-Design, Exploratory Study to Evaluate the Efficacy of fremanezumab in Subjects with Rosacea

First published: 15/06/2021

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS41590

Study ID

46596

DARWIN EU® study

No

Study countries

United States

Study description

Lay language title: A study of fremanezumab in patients with moderate to severe rosacea Phase 1b interventional study Inclusion: Males and non-pregnant females with moderate or severe rosacea, 18 years and older Exclusion: Other rosacea treatments within 14 days Known sensitivity to fremanezumab Study completion expected November 2021 IPD sharing statement: 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 email USMedInfo@tevapharm.com to make your request.

Study status

Finalised

Contact details

Study institution contact

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Study contact

juline.bryson@tevapharm.com

Primary lead investigator

Juline Bryson

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 06/01/2021

Actual: 02/02/2021

Study start date
Planned: 16/06/2021

Actual: 16/06/2021

Date of final study report
Planned: 15/02/2022

Actual: 22/03/2022

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

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Clinical trial

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To compare efficacy of active medication over placebo

Study Design

Clinical trial phase

Human pharmacology (Phase I)

Clinical trial randomisation

Randomised clinical trial

Study drug and medical condition

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

FREMANEZUMAB

Medical condition to be studied

Rosacea

Population studied

Short description of the study population

The study included males and non-pregnant females aged 18 years or older with moderate or severe rosacea.

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)

Special population of interest

Other

Special population of interest, other

Patients with rosacea

Estimated number of subjects

40

Study design details

Outcomes

Proportion of patients considered a treatment success in each group (test and placebo), Number of patients with adverse events in each group

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