

Fezolinetant Experience for the Treatment of Vasomotor Symptoms Associated with Menopause Among Women in a German Real-life Setting

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Study

Ongoing

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/1000000132>

EU PAS number

EUPAS1000000132

Study ID

1000000132

DARWIN EU® study

No

Study countries

☐ Germany

Study description

This study is for women in Germany who are going through menopause. They have symptoms including hot flashes and night sweats (also called vasomotor symptoms). Their doctor has decided to give them fezolinetant tablets to help treat these symptoms. Fezolinetant tablets do not contain hormones.

Fezolinetant tablets have been approved in some countries to treat hot flashes and night sweats.

Study status

Ongoing

Research institutions and networks

Institutions

[Astellas Pharma Europe Ltd.](#)

Contact details

Study institution contact

Clinical Trial Registration Department

[Study contact](#)

clinicaltrialregistration@astellas.com

Primary lead investigator

Regina Schaetzle

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/07/2024

Study start date

Actual: 18/06/2024

Data analysis start date

Planned: 07/01/2026

Date of final study report

Planned: 30/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe Ltd.

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

2693-MA-3549

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)
Evaluation of patient-reported outcomes
Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This is a decentralized clinical trial, single arm prospective study using Real World Evidence with no Biospecimen Retention.

Main study objective:

The goal of this study is to learn about the value of fezolinetant tablets in treating hot flashes and night sweats that women in Germany experience during menopause.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

VEOZA

Anatomical Therapeutic Chemical (ATC) code

(G02CX06) fezolinetant

fezolinetant

Medical condition to be studied

Menopausal symptoms

Population studied

Short description of the study population

The study population will consist of women who are experiencing VMS and have been prescribed fezolinetant for the treatment of VMS associated with menopause via an independent decision by the treating physician as per routine clinical practice.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Menopausal women

Estimated number of subjects

334

Study design details

Setting

The women that want to take part in the study will take fezolinetant tablets for their hot flashes and night sweats. This study is about collecting information

only. The individual's doctor decides on treatment, not the study sponsor (Astellas).

The study will last about 6 months (24 weeks). During the study, the women taking part will complete up to 5 virtual reviews. The virtual reviews will ask the women to complete 3 – 5 surveys. At the first virtual review the women will be asked about their health and other medicines they have taken or are taking. The surveys will ask the women about their hot flashes and night sweats, other menopause symptoms, and how these symptoms affect their health and daily life. After the first or second virtual review the women will take their first dose of fezolinetant tablets and continue taking fezolinetant as explained by their doctor. The women will have 3 virtual follow-up reviews at about 1 week, 3 months (12 weeks), and 6 months (24 weeks) after their first dose of fezolinetant tablets. The women will be asked when they took their fezolinetant tablets or if they stopped taking them.

Comparators

None

Outcomes

Primary:

- Response of “moderately better” or “much better” at week 24, measured by Patient Global Impression of Change of Vasomotor Symptoms (PGI-C VMS)

Secondary:

- Response of “moderately better” or “much better” at week 1 and week 12, measured by PGI-C VMS
- Change on the Menopause-Specific Quality of Life Domain (MENQoL) 1-week recall vasomotor symptoms (VMS) domain score from baseline to week 12 and

from baseline to week 24

- Change on the MENQOL 1-week recall total score (full questionnaire) from baseline to week 12 and from baseline to week 24
 - Response of “moderately better” or “much better” at weeks 1, 12 and 24, measured by the Patient Global Impression of Change of Sleep Disturbance (PGI-C SD)
 - Change on the Patient-Reported Outcomes Measurement Information System, Sleep Disturbance - short Form 8b (PROMIS SD SF 8b) total score from baseline to week 12 and from baseline to week 24
 - Response of “very satisfied”, “somewhat satisfied”, “undecided”, “somewhat unsatisfied” or “very unsatisfied” on treatment satisfaction at week 12 and week 24
 - Discontinuation of fezolinetant (yes/no)
 - Reason for discontinuation
 - Treatment switching for VMS associated with menopause (yes/no)
 - Occurrence of each adverse event (AE) (yes/no)
 - Occurrence of each SAE (yes/no)
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Data analysis plan

This is a single arm, non-interventional observational study, with no hypothesis testing. The sample size is based on primary estimands and assumes approximately 25% discontinuation prior to week 24.

The primary estimand is the Treatment Policy estimand, which ignores intercurrent events, including changes in treatment. Missing data will be imputed.

Supplemental analyses are proposed, to use a Hypothetical estimand (data occurring after intercurrent events are set to missing), and a Composite estimand (any occurrence of an intercurrent event leads to the participant

being considered a non-responder).

Data management

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