

Trial in Progress: Fezolinetant for VMS in a German Real-life Setting (GRACE)

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Objective

- To generate real-world evidence outcomes of fezolinetant 45 mg treatment for vasomotor symptoms (VMS) associated with menopause, including menopause-related quality of life; sleep; and safety, in the context of the German healthcare system

Conclusion

- GRACE will provide valuable real-world evidence on the efficacy and safety of fezolinetant for the treatment of VMS associated with menopause in Germany**

Introduction

- The most common and bothersome symptoms associated with menopause are VMS, characterized by hot flushes and/or night sweats
- VMS negatively impact quality-of-life, sleep, mood, and work productivity¹⁻⁴
- Hormone therapy is an effective treatment option but is not suitable for all women⁵
- Fezolinetant is a first-in-class, oral, nonhormonal, neurokinin 3 receptor antagonist that modulates neuronal activity in the thermoregulatory center in the hypothalamus. This inhibition leads to reductions in the frequency and severity of VMS associated with menopause⁶⁻⁸
- Fezolinetant is approved as a treatment option for moderate to severe VMS in many regions, including North America, Europe, Asia, and Australia, at a dose of 45 mg once daily⁷⁻¹²

E-poster

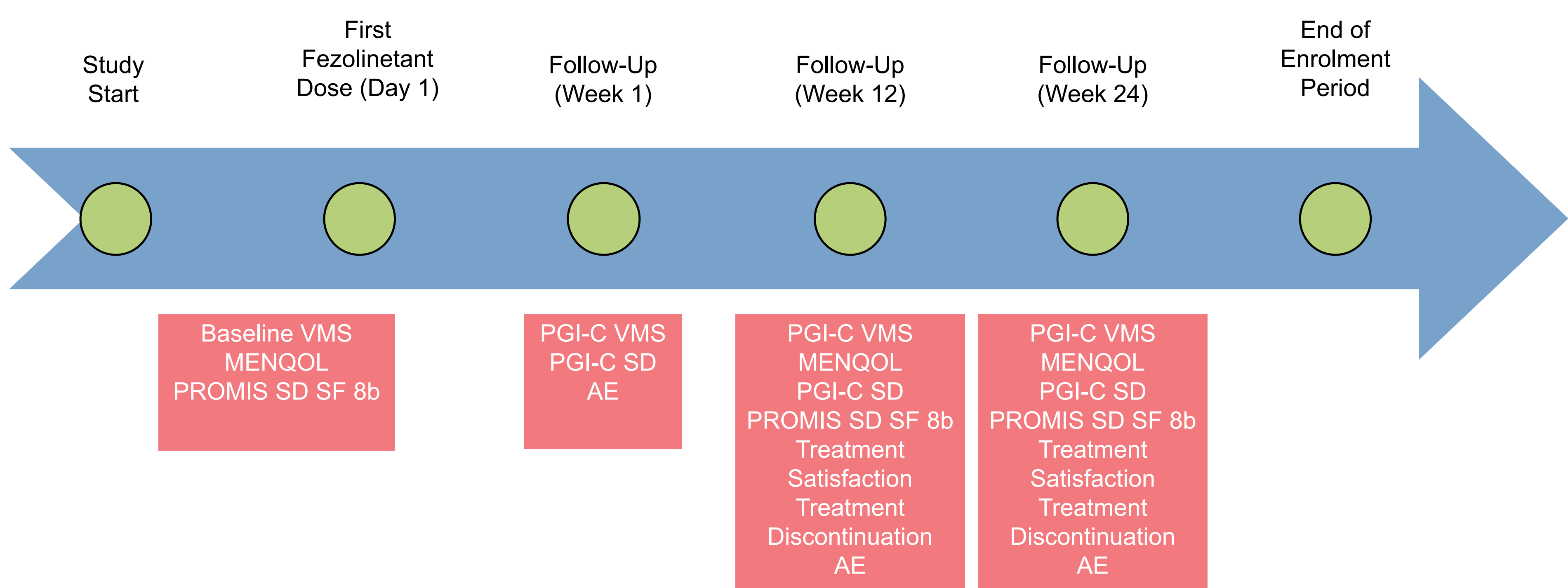
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Methods

- The Germany vasomotor evidence study, GRACE (HMA-EMA RWD number EUPAS1000000132), is a decentralized, longitudinal, single-arm, non-interventional, observational study at approximately 50 healthcare facilities
- It is designed to prospectively collect outcomes, remotely, from participants prescribed fezolinetant for treatment of VMS associated with menopause in a real-world setting in Germany
- Participants will be seen per routine clinical care and observed for 24 weeks following fezolinetant initiation (**GRACE Study Design**)
- Participants include women with VMS associated with menopause (target enrolment n=334) who are treated for the first time with fezolinetant 45 mg once daily in routine clinical practice

GRACE Study Design



AE, adverse event; MENQOL, Menopause-Specific Quality of Life Domain; PGI-C SD, Patient Global Impression of Change of Sleep Disturbance; PGI-C VMS, Patient Global Impression of Change of Vasomotor Symptoms; PROMIS SD SF 8b, Patient-Reported Outcomes Measurement Information System, Sleep Disturbance - Short Form 8b

Key Inclusion Criteria

- Prescribed fezolinetant for treatment of VMS associated with menopause according to routine clinical practice
- Living in Germany
- Able to communicate in German language
- Able to use digital tools and have access to an internet-capable device

Key Exclusion Criteria

- Participating in clinical trials

Study Objectives and Endpoints

- All data will be ascertained remotely via self-reported online questionnaires at specified weeks using an internet-capable device, such as a personal computer or mobile device

GRACE Primary and Secondary Objectives and Endpoints

Primary Objective	Primary Endpoint
To assess the percentage of participants reporting improvement in hot flushes/night sweats at week 24 after receiving fezolinetant for treatment of VMS associated with menopause	Response of “moderately better” or “much better” at week 24, measured by PGI-C VMS
Secondary Objectives	Secondary Endpoints
- To assess the percentage of participants reporting improvement in hot flushes/night sweats at weeks 1 and 12 in women initiating fezolinetant for the treatment of VMS associated with menopause - To assess change in VMS bother in women initiating fezolinetant for the treatment of VMS associated with menopause - To assess change in menopause-related quality of life in women initiating fezolinetant for the treatment of VMS associated with menopause - To assess change in sleep disturbance in women initiating fezolinetant for the treatment of VMS associated with menopause - To assess treatment satisfaction in women initiating fezolinetant for the treatment of VMS associated with menopause¹ - To describe discontinuation of fezolinetant and reasons for discontinuation (including potential switching patterns) in women initiating fezolinetant for the treatment of VMS associated with menopause - To describe the AE profile/rate in women initiating fezolinetant for the treatment of VMS associated with menopause²	- Response of “moderately better” or “much better” at weeks 1 and 12, measured by the PGI-C VMS - Change on the MENQOL 1-week recall VMS domain score from baseline to weeks 12 and 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 PGI-C SD - Change on the PROMIS SD SF 8b total score from baseline to weeks 12 and 24 - Response of “very satisfied,” “somewhat satisfied,” “undecided,” “somewhat unsatisfied,” or “very unsatisfied” on treatment satisfaction at weeks 12 and 24 - Discontinuation of fezolinetant (Y/N) - Reason for discontinuation - Treatment switching for VMS associated with menopause (Y/N) - Occurrence of each AE (Y/N) - Occurrence of each SAE (Y/N)

¹Treatment satisfaction will be assessed using one question that will be created for this study
²AEs and SAEs will be collected at any time point from the time of signing the Informed Consent Form up to 24 weeks after the first dose of fezolinetant
AE, adverse event; MENQOL, Menopause-Specific Quality of Life Domain; N, no; PGI-C SD, Patient Global Impression of Change of Sleep Disturbance; PGI-C VMS, Patient Global Impression of Change of Vasomotor Symptoms; PROMIS SD SF 8b, Patient-Reported Outcomes Measurement Information System, Sleep Disturbance - Short Form 8b; SAE, serious adverse event; VMS, vasomotor symptoms; Y, yes

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Disclosures

KH: employee of ZEG - Berlin Center for Epidemiology and Health Research, GmbH, Berlin, Germany, and the principal investigator of the GRACE study.
RS, MB, LC, LK, SJ, KM: employees of Astellas Pharma Inc.