Trial-in-progress: Real-world sleep outcomes among women with vasomotor symptoms associated with menopause using fezolinetant (ADELE-AU)

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Objective

To investigate sleep outcomes among women receiving fezolinetant treatment for moderate to severe vasomotor symptoms (VMS) associated with menopause in real-world Australian clinical practice

Conclusion

ADELE-AU is designed to provide valuable real-world evidence for the treatment of moderate to severe VMS associated with menopause with fezolinetant in the context of Australian clinical practice

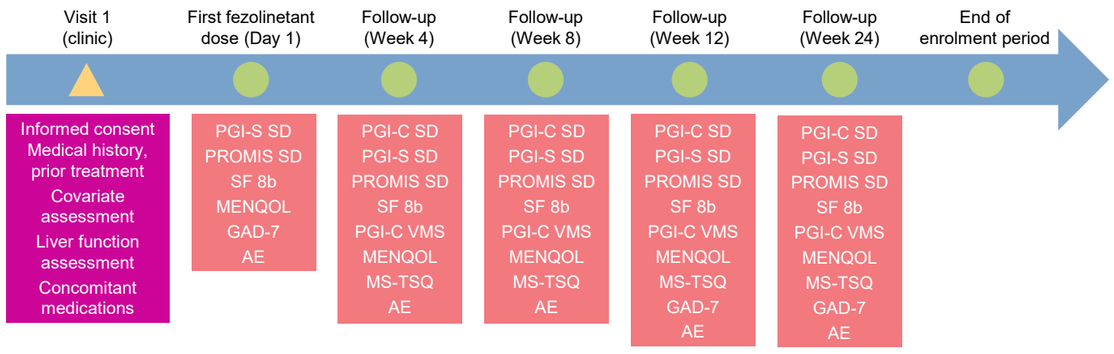
Introduction

- VMS, characterised by hot flushes and night sweats, are reported by up to 80% of women experiencing menopause[1]
- Moderate to severe VMS associated with menopause have adverse effects on concentration, energy levels, overall quality of life, and sleep[2]
  - Despite this, about 85% of Australian women experiencing VMS do not receive treatment[3]
- Fezolinetant, an oral, nonhormonal, neurokinin 3 receptor antagonist treatment for moderate to severe VMS, is approved at a dose of 45 mg once daily in many regions including North America, Europe, Asia, and Australia[4-9]
  - The phase 3 SKYLIGHT 1 (NCT04003155) and SKYLIGHT 2 (NCT04003142) studies established the efficacy, safety, and tolerability of fezolinetant in treating moderate to severe VMS associated with menopause[10-11]
  - A pooled analysis of the SKYLIGHT studies showed that fezolinetant treatment also improved patient-reported sleep disturbance and impairment[12]

Methods

- A real-world observational study describing sleep outcomes among women with vasomotor symptoms associated with menopause using fezolinetant in Australia (ADELE-AU) is an observational, longitudinal, prospective, multicenter, single-arm study
- Participants include women aged ≥40 years who initiate fezolinetant for the treatment of moderate to severe VMS with sleep disturbances per routine clinical practice
- The study was initiated in May 2025 with a duration of 24 weeks. Questionnaires are administered online via the study portal
- The study aims to recruit a minimum of **100 women** receiving treatment from endocrinologists, obstetricians, and general practitioners in metropolitan settings across Australia

ADELE-AU study design



AE, adverse event; MENQOL, Menopause-specific Quality of Life; GAD-7, Generalized Anxiety Disorder Assessment-7; MS-TSQ, Menopause Symptoms Treatment Satisfaction Questionnaire; PGI-C SD, Patient Global Impression of Change Sleep Disturbance; PGI-C VMS, Patient Global Impression of Change Vasomotor Symptoms; PROMIS SD SF 8b, Patient-Reported Outcomes Measurement Information System Sleep Disturbance – Short Form 8b

Key Inclusion Criteria

- Women aged ≥40 years, living in Australia
- Experiencing moderate to severe VMS associated with menopause
- Experiencing moderate or severe sleep disturbances as measured by the PGI-C SD
- Prescribed fezolinetant in accordance with physician discretion and standard of care
- Able to use digital tools and have access to an internet-capable device

Key Exclusion Criteria

- Participation in other fezolinetant clinical trials or previously prescribed fezolinetant
- Any clinically diagnosed sleep condition with sleep disturbance as a symptom (eg, insomnia, narcolepsy)
- Taking medication to improve sleep disturbances

Study Objectives and Endpoints

- All data will be collected electronically from participants and healthcare providers via electronic case report forms
- Patient-reported outcome measures used in the study:
  - The Patient Global Impression of Severity Sleep Disturbance (PGI-S SD) rates the severity of sleep disturbance
  - The Patient Global Impression of Change Sleep Disturbance (PGI-C SD) measures the change in clinical status in sleep disturbance
  - The Patient Global Impression of Change Vasomotor Symptoms (PGI-C VMS) measures the change in clinical status in VMS
  - The Patient-Reported Outcomes Measurement Information System Sleep Disturbance – Short Form 8b (PROMIS SD SF 8b) measures sleep disturbance
  - The Menopause-specific Quality of Life (MENQOL) assesses quality of life related to menopause symptoms
  - The Menopause Symptoms Treatment Satisfaction Questionnaire (MS-TSQ) measures satisfaction with treatment for menopause symptoms
  - The Generalized Anxiety Disorder Assessment-7 (GAD-7) assesses worry and anxiety symptoms
- Treatment-emergent adverse events (AEs) will be reported directly by the treating healthcare provider

ADELE-AU Primary, Secondary, and Exploratory Objectives and Endpoints

Primary Objective	Primary Endpoint
• To assess the percentage of women reporting improvement in sleep disturbance at week 12	• Response of "moderately better" or "much better" on the PGI-C SD at week 12

Secondary Objectives	Secondary Endpoints
• To assess the percentage of women reporting improvement in sleep disturbance at week 24	• Response of "moderately better" or "much better" on the PGI-C SD at week 24
• To assess the change in sleep disturbance at weeks 12 and 24	• Change in sleep disturbance raw score on the PROMIS SD SF 8b from baseline to weeks 12 and 24 • Change in sleep disturbance t-score on the PROMIS SD SF 8b from baseline to weeks 12 and 24
• To assess the percentage of women with meaningful change in sleep disturbance, approximated by psychometric evaluation at weeks 12 and 24	• Responder on the PROMIS SD SF 8b: ≥8-point reduction (improvement) in the raw score from baseline to week 12 • Responder on the PROMIS SD SF 8b: ≥10-point reduction (improvement) in the t-score from baseline to week 12 • Responder on the PGI-S SD: ≥1-unit improvement from baseline to week 12 • Responder on the PGI-S SD: ≥2-unit improvement from baseline to week 12 • Responder on the PROMIS SD SF 8b: ≥8-point reduction (improvement) in the raw score from baseline to week 24 • Responder on the PROMIS SD SF 8b: ≥10-point reduction (improvement) in the t-score from baseline to week 24 • Responder on the PGI-S SD: ≥1-unit improvement from baseline to week 24 • Responder on the PGI-S SD: ≥2-unit improvement from baseline to week 24
• To assess the change in menopause-related quality of life	• Change in the MENQOL 1-week recall total score (full questionnaire) from baseline to weeks 12 and 24 • Change in individual MENQOL domain scores (vasomotor, psychosocial, physical, and sexual bother) from baseline to weeks 12 and 24
• To assess the percentage of women reporting improvement in hot flushes/night sweats at weeks 12 and 24	• Improvement in hot flushes/night sweats measured by response of "moderately better" or "much better" at weeks 12 and 24 on the PGI-C VMS
• To describe treatment satisfaction	• Total satisfaction score at weeks 12 and 24 on the MS-TSQ
• To describe the AE profile/rate	• AEs reported by women and/or treating physician • Types of AEs • Duration and timing of AEs • Relationship to treatment • Action taken due to AEs • Outcome of AEs • Abnormal laboratory findings • Subgroup analysis
• To describe treatment pattern, reasons for initiating, discontinuation, and reasons for discontinuing (including potential switching patterns)	• Treatment patterns – Fezolinetant treatment persistence within study population, median duration (in days) from initiation to discontinuation/end of study – Percentage of women who discontinue fezolinetant treatment during the study period – Fezolinetant persistence within women who discontinue treatment during the study period, median duration (in days) from initiation to the point of discontinuation • Reasons for initiating fezolinetant • Reasons for fezolinetant discontinuation

AE, adverse event; MENQOL, Menopause-specific Quality of Life; MS-TSQ, Menopause Symptoms Treatment Satisfaction Questionnaire; PGI-C SD, Patient Global Impression of Change Sleep Disturbance; PGI-C VMS, Patient Global Impression of Change Vasomotor Symptoms; PROMIS SD SF 8b, Patient-Reported Outcomes Measurement Information System Sleep Disturbance – Short Form 8b; VMS, vasomotor symptoms

- Additional exploratory objectives included:
  - Change in sleep disturbance at weeks 4 and 8
  - Change in MENQOL
  - Percentage of women with improved hot flushes/night swears at weeks 4 and 8
  - Treatment satisfaction at weeks 4 and 8
  - Change in anxious symptoms at weeks 12 and 24

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Disclosures

Elizabeth Rayment: honoraria from AMS. Christine Kemp, Marcos Freire, Farid Abdul Hadi, Daniel Bin Ng: employees of Astellas Pharma Inc. Priscila Roch, Emma Peffer: employees of IQVIA. Natassia Rodrigo: Astellas Pharma, NSW Health.

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