

## Press Release

### **China's National Medical Products Administration Accepts New Drug Application for VEOZA™ (fezolinetant) for the Treatment of Moderate to Severe Vasomotor Symptoms Associated with Menopause**

**TOKYO, October 27, 2026** – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, “Astellas”) today announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has accepted a New Drug Application (NDA) for VEOZA™ (fezolinetant 45 mg) seeking approval for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.

VMS, commonly known as hot flashes and night sweats, are among the most common symptoms associated with menopause and can significantly affect women's sleep, daily activities and overall quality of life.<sup>1</sup> 55% of women aged 40-65 years across East Asia, including Mainland China, have experienced moderate to severe VMS, underscoring the significant burden of menopausal symptoms and the continued need for effective treatment options.<sup>2</sup>

The NDA submission is supported by data from the global Phase 3 BRIGHT SKY™ program, a new bridging study conducted in China and the previously completed clinical studies in China.<sup>3</sup> Across all programmes, fezolinetant was generally well tolerated, with the most commonly reported adverse events including headache, abdominal pain, diarrhoea, insomnia and back pain.

Fezolinetant is a non-hormonal, selective neurokinin 3 (NK3) receptor antagonist specifically designed to block neurokinin B binding on kisspeptin/neurokinin/dynorphin neurons, which are involved in regulating the brain's temperature control center. By targeting this pathway, fezolinetant helps reduce the frequency and severity of moderate to severe VMS associated with menopause.<sup>4,5</sup> Fezolinetant is currently approved in 50 countries worldwide.

Astellas remains committed to advancing women's health and expanding access to evidence-based treatment options for moderate to severe VMS associated with menopause.

Astellas has already factored the impact of this matter into its financial forecast for the current fiscal year ending March 31, 2027.

**About VEOZA™ (fezolinetant 45 mg)**

VEOZA (fezolinetant 45 mg) is a selective neurokinin 3 receptor (NK3R) antagonist, currently approved in 50 countries for the treatment of moderate to severe VMS associated with menopause. VEOZA is not currently approved in China. Fezolinetant is specifically designed to block neurokinin B (NKB) binding on the kisspeptin/neurokinin/dynorphin (KNDy) neuron, helping modulate neuronal activity in the brain's temperature control center, the hypothalamus, to reduce the number and intensity of hot flushes and night sweats.

**About the BRIGHT SKY™ Phase 3 Program**

The BRIGHT SKY pivotal trials, SKYLIGHT 1™ (NCT04003155) and SKYLIGHT 2™ (NCT04003142), enrolled over 1,000 women with moderate to severe VMS. The trials are double-blinded, placebo-controlled for the first 12 weeks followed by a 40-week treatment extension period. Women were enrolled at over 180 sites within the U.S., Canada and Europe. SKYLIGHT 4™ (NCT04003389) is a 52-week double-blinded, placebo-controlled study designed to investigate the long-term safety of fezolinetant. For SKYLIGHT 4, over 1,800 women with VMS were enrolled at over 180 sites within the U.S., Canada and Europe.

**About Phase 2 Clinical Study in China**

The Phase 2, randomized, placebo-controlled, double-blind, 12-week study (NCT06812754) assessed the efficacy and safety of fezolinetant 45 mg in Chinese women suffering from moderate to severe vasomotor symptoms associated with menopause. A total of 150 women were randomized to receive fezolinetant 45 mg or placebo. The primary end point was the efficacy and safety of fezolinetant 45 mg versus placebo on the frequency of moderate to severe hot flushes and night sweats after 12 weeks of treatment.

**About MOONLIGHT 1™**

The Phase 3 study (2693-CL-0305) was a randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of fezolinetant 30 mg in women with moderate to severe vasomotor symptoms associated with menopause. The study enrolled 302 women across mainland China, Taiwan and South Korea and included a 12-week placebo-controlled treatment period followed by a 12-week active treatment extension period.

**About MOONLIGHT 3™**

The Phase 3 long-term safety study (2693-CL-0307) was a single-arm, multicentre trial evaluating the safety and tolerability of fezolinetant 30 mg in women in China with vasomotor symptoms associated with menopause. The study enrolled 150 women in China and assessed long-term safety following up to 52 weeks of treatment with fezolinetant.

**About Astellas**

Astellas is a global life sciences company committed to turning innovative science into VALUE for patients. We provide transformative therapies in disease areas that include oncology, ophthalmology, urology, immunology, and women's health. Through our research and development programs, we are pioneering new healthcare solutions for diseases with high unmet medical needs. Learn more at [www.astellas.com](http://www.astellas.com).

**Cautionary Notes**

In this press release, statements made with respect to current plans, estimates, strategies and beliefs, and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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**References**

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2. Tuomikoski P, Ylikorkala O, Mikkola TS, et al. Epidemiology and prevalence of menopausal symptoms in East Asian women.
3. Fraser GL, Lederman S, Waldbaum A, et al. Effect of fezolinetant on moderate to severe vasomotor symptoms associated with menopause: results from the SKYLIGHT 1 phase 3 randomised controlled study. *Lancet*. 2023;401:1091-1102.
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5. Astellas Pharma Inc. VEOZA™ (fezolinetant) Company Core Data Sheet / Prescribing Information. Current version.