Press Release

# Astellas Receives Positive CHMP Opinion for VEOZA™ (fezolinetant)

*Fezolinetant is an investigational nonhormonal treatment for vasomotor symptoms (VMS) associated with menopause*

*More than half of women ages 40 to 64 worldwide experience VMS, with rates in Europe ranging from 56% to 97%[1,2,3]*

**TOKYO, October 13, 2023** – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on October 12 adopted a positive opinion relating to the use of VEOZA™ (fezolinetant) 45 mg once daily for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.[4] VMS, also known as hot flashes and/or night sweats, are common symptoms of menopause.[5,6]

**If approved by the European Commission (EC), fezolinetant will be a first-in-class, nonhormonal treatment option to reduce moderate to severe VMS associated with menopause.** Fezolinetant works by blocking neurokinin B (NKB) binding on the kisspeptin/neurokinin B/dynorphin (KNDy) neuron, helping restore the balance in the brain's temperature control center (the hypothalamus) to reduce the number and intensity of hot flashes and night sweats.

**Marci English, Vice President, Head of BioPharma Development, Astellas**
"Today's positive CHMP opinion marks another significant milestone for both fezolinetant and women's health. We are excited to be another step closer to potentially providing a novel and important treatment option to individuals in Europe suffering from moderate to severe VMS associated with menopause."

The positive CHMP opinion is based on the results from the BRIGHT SKY™ program, which included three Phase 3 clinical trials that collectively enrolled over 3,000 individuals across Europe, the U.S. and Canada. Results from the SKYLIGHT 1™ and SKYLIGHT 2™ pivotal trials characterize the efficacy and safety of fezolinetant for the treatment of moderate to severe VMS associated with menopause and were published in *The Lancet* and *The Journal of Clinical Endocrinology & Metabolism*, respectively.[7,8] Data from the SKYLIGHT 4™ safety study further characterizes the long-term safety profile of fezolinetant and was published in *Obstetrics & Gynecology*.[9]

The positive opinion will now be reviewed by the EC, which has the authority to approve medicines for European Union member states, as well as Iceland, Norway, Liechtenstein and Northern Ireland.[10] The EC has 67 days from the CHMP opinion to issue a final decision. Additionally, the positive opinion allows the submission of a European Commission Decision Reliance Procedure marketing authorization application to the Medicines and Healthcare products Regulatory Agency (MHRA), which has the authority to approve

medicines for England, Wales and Scotland following the UK's transition from the European Union.[11] A final MHRA decision is anticipated in the coming months.

Astellas has already reflected the impact from this result in its financial forecast of the current fiscal year ending March 31, 2024.

For more information, please see the press release "European Medicines Agency Accepts Astellas' Marketing Authorization Application for Fezolinetant" issued on September 29, 2022.

**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 Europe, the U.S. and Canada. 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 Europe, the U.S. and Canada.

**About VMS Associated with Menopause**
VMS, characterized by hot flashes (also called hot flushes) and/or night sweats, are common symptoms of menopause.[5,6] Worldwide, more than half of women 40 to 64 years of age experience VMS with rates in Europe ranging from 56% to 97%.[1,2,3] The prevalence of moderate to severe VMS in postmenopausal women in Europe has been reported at 40%.[12] VMS can have a disruptive impact on women's daily activities and overall quality of life.[5]

**About Fezolinetant**
Fezolinetant is an investigational oral, nonhormonal medicine in clinical development for the treatment of moderate to severe VMS associated with menopause. VMS are also known as hot flashes or night sweats. Fezolinetant works by blocking neurokinin B (NKB) binding on the kisspeptin/neurokinin/dynorphin (KNDy) neuron, helping restore the balance in the brain's temperature control center (the hypothalamus) to reduce the number and intensity of hot flashes and night sweats.[13,14,15] There is no guarantee the agent will receive regulatory approval in Europe or become commercially available for the uses being investigated.

**About Astellas**
Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+® healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into VALUE for patients. For more information, please visit our website at https://www.astellas.com/en.

**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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