Press Release

Astellas' VEOZA™ (fezolinetant) Approved by European Commission for Treatment of Vasomotor Symptoms Associated with Menopause

First-in-class treatment option reduces number and intensity of hot flashes and night sweats

TOKYO, December 11, 2023 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced the European Commission (EC) on December 7 approved VEOZA™ (fezolinetant) 45 mg once daily for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.

VMS, also known as hot flashes and/or night sweats, are common symptoms of menopause.[1,2] Worldwide, more than half of women 40 to 64 years of age experience VMS, with rates in Europe ranging from 56% to 97%.[3,4,5] The prevalence of moderate to severe VMS in postmenopausal women in Europe has been reported at 40%.[6] VMS can have a disruptive impact on women's daily activities and overall quality of life.[2]

Prof. Rossella Nappi, Full Professor of Obstetrics and Gynecology, Chief of the Research Center for Reproductive Medicine and Director of the Gynecological Endocrinology & Menopause Unit, IRCCS San Matteo Foundation, University of Pavia
"I've been awaiting the marketing authorization of fezolinetant. I'm happy to see this advancement in women's health and that my patients will soon have this new nonhormonal treatment option available to better control their moderate to severe VMS."

Marci English, Vice President, Head of BioPharma Development, Astellas
"Fezolinetant's novel mechanism of action targets the root cause of moderate to severe VMS associated with menopause. We are proud to have developed an innovative treatment option for a condition that has lacked scientific advancement for too long and look forward to making fezolinetant available in countries across the European Union."

Before menopause, there is a balance between estrogens, a female sex hormone, and a protein made by the brain known as neurokinin B (NKB) that regulates the brain's temperature control center. As the body goes through menopause, estrogen levels decline and this balance is disrupted, which can lead to VMS. By blocking NKB binding in the temperature control center, fezolinetant reduces the number and intensity of hot flashes and night sweats.

This approval follows a positive opinion issued in October by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) based on the results from the BRIGHT SKY™ program, which included three Phase 3 clinical trials as part of a development program that collectively enrolled over 3,000 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 EC marketing authorization for fezolinetant is applicable in the European Union (EU) Member States, as well as Iceland, Norway and Liechtenstein.[10] Fezolinetant was also approved in Switzerland on December 4, 2023.

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

For more information, please see the press releases "European Medicines Agency Accepts Astellas' Marketing Authorization Application for Fezolinetant" issued on September 29, 2022, and "Astellas Receives Positive CHMP Opinion for VEOZA™ (fezolinetant)" issued on October 13, 2023.

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 VEOZA™ (fezolinetant)
VEOZA (fezolinetant) is a nonhormonal neurokinin 3 (NK3) receptor antagonist indicated in the EU and European Economic Area countries for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause. VMS are also known as hot flashes or night sweats. VEOZA works by blocking neurokinin B (NKB) binding on the kisspeptin/neurokinin/dynorphin (KNDy) neuron to modulate neuronal activity in the brain's temperature control center (the hypothalamus) to reduce the number and intensity of hot flashes and night sweats.[11,12,13]

Important Safety Information
The full European Summary of Product Characteristics (SPC/SmPC) for fezolinetant will be available from the European Medicines Agency at www.ema.europa.eu.

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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