Press Release

Astellas Provides Update on Fezolinetant New Drug Application in U.S.

TOKYO, February 20, 2023 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced the U.S. Food and Drug Administration (FDA) notified the company that it is extending the original priority review Prescription Drug User Fee Act (PDUFA) goal date for fezolinetant, an investigational agent for the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause. Astellas was notified on February 17, 2023, that the FDA is extending the PDUFA goal date by three months, to May 22, 2023, to allow more time to complete their review.

"We remain confident in the clinical profile of fezolinetant and the potential benefits it could bring to women experiencing moderate to severe VMS due to menopause, and we will continue to work with the FDA on its review of the NDA for fezolinetant," said Ahsan Arozullah, M.D., M.P.H., Senior Vice President and Head of Development Therapeutic Areas, Astellas.

The impact of this matter on Astellas' financial results of the current fiscal year ending March 31, 2023, is expected to be minor.

For more information, please see the press release "U.S. FDA Accepts Astellas' New Drug Application for Fezolinetant" issued on August 18, 2022.

About Fezolinetant
Fezolinetant is an investigational oral, nonhormonal therapy in clinical development for the treatment of moderate to severe VMS due to menopause. Fezolinetant works by blocking neurokinin B (NKB) binding on the kisspeptin/neurokinin B/dynorphin (KNDy) neuron to modulate neuronal activity in the thermoregulatory center of the brain (the hypothalamus) to reduce the frequency and severity of moderate to severe VMS due to menopause.[1,2,3] The safety and efficacy of fezolinetant are under investigation and have not been established. There is no guarantee the agent will receive regulatory approval 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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[2] Fraser GL, Lederman S, Waldbaum A, et al. A phase 2b, randomized, placebo-controlled, double-blind, dose-ranging study of the neurokinin 3 receptor antagonist fezolinetant for vasomotor symptoms associated with menopause. Menopause. 2020;27:382-392.

[3] Fraser GL, Hoveyda HR, Clarke IJ, et al. The NK3 receptor antagonist ESN364 interrupts pulsatile LH secretion and moderate levels of ovarian hormones throughout the menstrual cycle. Endocrinology. 2015;156:4214-4225.