Press Release

U.S. FDA Accepts Astellas' New Drug Application for Fezolinetant

If approved by the FDA, fezolinetant would be a nonhormonal treatment for moderate to severe vasomotor symptoms associated with menopause

TOKYO, August 18, 2022 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's New Drug Application (NDA) for fezolinetant, an investigational oral, nonhormonal compound seeking approval for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause. VMS, characterized by hot flashes and/or night sweats, are common symptoms of menopause.[1,2]

The PDUFA target action date is February 22, 2023, following use of a priority review voucher (PRV). Astellas booked ¥13.1 billion of amortization of the intangible asset relating to PRV as R&D expense in the first quarter of fiscal year 2022.

"The FDA's acceptance of our NDA for fezolinetant brings us one step closer to advancing care for women in the U.S. who experience VMS," said Ahsan Arozullah, M.D., M.P.H., Senior Vice President and Head of Development Therapeutic Areas, Astellas. "We look forward to the FDA's review of our application, and the potential to offer a first-in-class nonhormonal treatment option to reduce the frequency and severity of moderate to severe VMS associated with menopause."

The NDA is supported by results from the BRIGHT SKY™ program, which included three Phase 3 clinical trials that collectively enrolled over 2,800 women with VMS across the U.S., Canada and Europe. 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. Data from the SKYLIGHT 4™ safety study further characterizes the long-term safety profile of fezolinetant. Within the NDA, Astellas proposes a 45 mg daily dose, which is subject to the FDA's review.

Fezolinetant is an investigational nonhormonal selective neurokinin 3 (NK3) receptor antagonist. The safety and efficacy of fezolinetant are under investigation and have not been established.

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

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 VMS Associated with Menopause
VMS, characterized by hot flashes (also called hot flushes) and/or night sweats, are common symptoms of menopause.[1,2] In the U.S., about 60% to 80% of women experience these symptoms during or after the menopausal transition and, worldwide, more than half of women 40 to 64 years of age experience VMS.[3,4,5,6] VMS can have a disruptive impact on women's daily activities and overall quality of life.[1]

About Fezolinetant
Fezolinetant is an investigational oral, nonhormonal therapy in clinical development for the treatment of moderate to severe VMS associated with menopause. Fezolinetant works by blocking neurokinin B (NKB) binding on the kisspeptin/neurokinin/dynorphin (KNDy) neuron to moderate neuronal activity in the thermoregulatory center of the brain (the hypothalamus) to reduce the frequency and severity of moderate to severe VMS associated with menopause.[7,8,9] 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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