Press Release

Astellas Initiates Phase 3 Clinical Studies of Fezolinetant for VMS Associated with Menopause in Japan

TOKYO, March 4, 2024 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced dosing of the first patient in the STARLIGHT™ 2 Phase 3 pivotal study for fezolinetant, an investigational oral, nonhormonal compound being studied for the treatment of vasomotor symptoms (VMS) associated with menopause in Japanese women.

In Japan, two Phase 3 clinical studies are underway. STARLIGHT 2 is evaluating the efficacy and safety of fezolinetant once-daily through 12 weeks. STARLIGHT 3 is evaluating the safety and tolerability of fezolinetant once-daily through 52 weeks.

Marci English, Vice President, Head of BioPharma Development, Astellas
"VMS associated with menopause affects millions of women in Japan. We are excited the STARLIGHT Phase 3 clinical studies are underway, bringing us one step closer to making this novel, nonhormonal treatment option available in Japan for women experiencing VMS associated with menopause."

Dosing for the STARLIGHT Phase 3 clinical studies was determined based on available global data, including the STARLIGHT Phase 2b study (NCT05034042) that enrolled 147 patients and completed in 2022. Primary results of STARLIGHT Phase 2b were presented at the Annual Meeting of the Japan Society for Menopause and Women's Health on Dec. 3, 2023.

About STARLIGHT 2
STARLIGHT 2 (NCT06206408) is a 12-week randomized, double-blind, placebo-controlled, parallel-group, multicenter clinical study to evaluate the superiority of fezolinetant versus placebo and assess the safety of fezolinetant in Japanese women experiencing VMS associated with menopause. Approximately 390 participants will be randomized to this study with 130 participants per treatment arm (fezolinetant low dose, fezolinetant high dose or placebo). The primary endpoint is mean change in the frequency of VMS from baseline to week 8, with total treatment duration of 12 weeks.

About STARLIGHT 3
STARLIGHT 3 (NCT06206421) is a 52-week randomized, double-blind, placebo-controlled, parallel-group, multicenter clinical study to assess the safety and tolerability of fezolinetant in Japanese women experiencing VMS associated with menopause. Approximately 260 participants will be randomized to this study with 130 participants per treatment arm (fezolinetant or placebo). The primary endpoint is frequency and severity of adverse events through 52 weeks.

About VMS
VMS, also known as hot flashes and/or night sweats, are common symptoms of menopause that can have a disruptive impact on women's daily activities and overall quality of life.[1,2] Worldwide, more than half of women 40 to 64 years of age experience VMS.[3,4] In Japan, about 25% to 37% of women experience these symptoms during or after the menopausal transition.[5,6]

About Fezolinetant
Fezolinetant is an investigational oral, nonhormonal medicine in clinical development in Japan for the treatment of 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.[7,8,9] There is no guarantee the agent will receive regulatory approval in Japan 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.

Contacts for inquiries or additional information:
Astellas Portfolio Communications
Anna Criddle
+1 (847) 682-4812
anna.criddle@astellas.com

Astellas Pharma Inc. Corporate Communications
+81-3-3244-3201

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