Press Release

Astellas Announces Positive Topline Results from Two Phase 3 Pivotal Global Trials of Fezolinetant for the Nonhormonal Treatment of Vasomotor Symptoms in Postmenopausal Women

TOKYO, February 19, 2021 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced positive topline results from the Phase 3 pivotal SKYLIGHT 1™ and SKYLIGHT 2™ clinical trials for fezolinetant, an investigational oral, nonhormonal compound being studied for the treatment of moderate to severe vasomotor symptoms (VMS) – i.e., hot flashes associated with menopause.

Both trials met all four co-primary endpoints showing statistically significant reduction from baseline in the frequency and severity of moderate to severe VMS to week 4 and week 12 for women who received fezolinetant 30 and 45 mg once-daily (QD) versus placebo. Serious treatment emergent adverse events (TEAE) occurred in less than 2 percent of patients and the most common TEAE was headache. SKYLIGHT 1 and SKYLIGHT 2 are ongoing studies, with patients completing a treatment duration for 52 weeks. Detailed results will be submitted for publication and for consideration at upcoming medical meetings following the 52-week analyses.

"We are encouraged by these results for fezolinetant, which mark the first Phase 3 data in a new category of selective neurokinin-3 (NK3)-targeted treatments for moderate to severe vasomotor symptoms," said Salim Mujais, M.D., Senior Vice President and Therapeutic Area Head, Medical Specialties, Astellas. "Vasomotor symptoms can add a significant burden and impact quality of life for women. We are hopeful that with fezolinetant, we will be able to deliver a novel nonhormonal treatment option."

VMS are the most common symptoms associated with menopause, affecting more than 50 percent of women 40 to 64 years of age.[1,2] VMS can have a considerable effect on a woman's comfort and sleep which can lead to fatigue, mood changes, and effect work and relationships.[1,3]

Fezolinetant is an investigational, selective neurokinin-3 receptor (NK3R) antagonist that blocks neurokinin B (NKB) binding on the kisspeptin/neurokinin/dynorphin (KNDy) neuron to moderate neuronal activity in the thermoregulatory center in the hypothalamus of the brain to treat VMS associated with menopause. If approved by regulatory authorities, fezolinetant would be a first-in-class, nonhormonal treatment option to reduce the frequency and severity of VMS associated with menopause.

SKYLIGHT 1 and SKYLIGHT 2 are double-blinded and placebo-controlled studies evaluating 30 and 45 mg fezolinetant administered once-daily for the first 12 weeks followed by 40-week active treatment extension periods.

About BRIGHT SKY™ PHASE 3 Program

The BRIGHT SKY pivotal trials, SKYLIGHT 1™ (NCT04003155) and SKYLIGHT 2™ (NCT04003142), have enrolled 1,028 women with moderate to severe vasomotor symptoms (VMS). The trials are double-blinded and placebo-controlled for the first 12 weeks followed by 40-week active treatment extension periods. Women were enrolled at 307 sites within the US, Canada and Europe. SKYLIGHT 4™ (NCT04003389), also underway, is a

52-week double-blinded and placebo-controlled study designed to investigate long-term safety of fezolinetant. For SKYLIGHT 4™, 1,833 women with VMS were enrolled at 216 sites within the US, Canada and Europe.

About Fezolinetant
Fezolinetant is an investigational oral, nonhormonal compound in clinical development for the potential treatment of moderate to severe VMS associated with menopause. Fezolinetant works by blocking NKB binding on the KNDy neuron to moderate neuronal activity in the thermoregulatory center of the brain to reduce the frequency and severity of VMS associated with menopause.

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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