Press Release

Astellas to Present VEOZA™ (fezolinetant) Data at IMS World Congress on Menopause

TOKYO, October 10, 2024 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") announced that VEOZA™ (fezolinetant)*, its first-in-class treatment for moderate to severe vasomotor symptoms (VMS) associated with menopause, will be featured in four oral and two poster presentations during the International Menopause Society (IMS) 19th World Congress on Menopause in Melbourne, Australia, October 19-22. VMS, also known as hot flashes and/or night sweats, are common symptoms of menopause.[1,2]

Marci English, Vice President, Head of BioPharma Development, Astellas
"Astellas is committed to advancing innovative science, and the data at the World Congress on Menopause further our understanding of how VMS impacts individuals and women's preferences for treatment. In addition, we are excited to share trial design for our recently initiated HIGHLIGHT study assessing fezolinetant for the treatment of moderate to severe VMS in patients with breast cancer taking adjuvant endocrine therapy."

Emad Siddiqui, M.D., Vice President, Head of Specialty Therapeutic Area for Medical Affairs, Astellas
"We are dedicated to continuing to expand the knowledge about fezolinetant beyond the pivotal trials. Our presentations at the World Congress on Menopause encompass a broad range of clinical and health-related quality of life analyses that further highlight the safety and efficacy of fezolinetant, as well as its positive impact on patient-reported outcomes including sleep and productivity at work."

Fezolinetant data will be featured in four oral and two poster presentations:

- Two oral presentations from the SKYLIGHT 1 and 2 studies focus on patient-reported sleep outcomes and impact on work productivity with fezolinetant (Menopause New Treatments 1 and 2; Monday, Oct. 21, 3:50-5:20 p.m.; A. Cano and R. Nappi, respectively).
- Two oral presentations from the DAYLIGHT study highlight response and quality of life in women treated with fezolinetant who are unsuitable for hormone therapy (Menopause New Treatments 1; Monday, Oct. 21, 3:50-5:20 p.m.; A. Hirschberg and M. Shapiro, respectively).
- Poster highlights analyses of clinical and nonclinical data demonstrating no association between fezolinetant treatment and incidence of malignant neoplasm (P073; Sunday, Oct. 20, 7:40-9 p.m.; M. Shapiro).
- Poster reviews study design for the recently initiated HIGHLIGHT 1 phase 3 clinical study designed to evaluate the efficacy and safety of fezolinetant for the treatment of moderate to severe VMS in women with stage 0 to 3 hormone receptor-positive breast cancer receiving adjuvant endocrine therapy (P055; Sunday, Oct. 20, 7:40-9 p.m.; P. Briggs).

Two additional oral presentations highlight Australian women's preferences for treatment of VMS associated with menopause and results of a literature review designed to identify and characterize concepts relevant to individuals' experiences of VMS with a goal of informing the development of a culturally sensitive self-assessment tool for VMS.

*VEOZA: Approved as “VEOZAH™” in U.S.

About the BRIGHT SKY™ Phase 3 Program
The BRIGHT SKY pivotal trials, SKYLIGHT 1™ (NCT04003155) and SKYLIGHT 2™ (NCT04003142), enrolled over 1,000 menopausal 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 menopausal women with VMS were enrolled at over 180 sites within the U.S., Canada and Europe.

About DAYLIGHT
DAYLIGHT (NCT05033886) is a Phase 3b, randomized, double-blind, placebo-controlled, 24-week study to assess the efficacy and safety of fezolinetant in menopausal women aged 40-65 suffering from moderate to severe VMS and considered unsuitable for hormone therapy. A total of 453 women were enrolled at 69 sites in Canada, Europe and Turkey.

About HIGHLIGHT 1™
HIGHLIGHT 1 (NCT06440967) is a randomized, placebo-controlled, double-blind, Phase 3 clinical study to assess the efficacy and safety of fezolinetant for the treatment of moderate to severe VMS in women with stage 0 to 3 hormone receptor-positive breast cancer who are receiving adjuvant endocrine therapy. Approximately 540 participants are planned to be randomized 1:1 to fezolinetant or placebo at up to 100 sites in Europe and Canada. The four coprimary endpoints are change in the frequency and severity of moderate to severe VMS from baseline to weeks 4 and 12. Patients will be treated for 52 weeks with a final evaluation at 55 weeks.

About VEOZA™ (fezolinetant)
VEOZA (fezolinetant) is a nonhormonal neurokinin 3 (NK3) receptor antagonist indicated in Australia for the treatment of moderate to severe vasomotor symptoms (hot flashes and night sweats) associated with menopause. 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.[3,4,5]

Important Safety Information
The full Australian Product Information and Australian Public Assessment Report (AusPAR) for fezolinetant is available from the Australian Government Therapeutic Goods Administration.

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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