Press Release

Astellas Announces Topline 12-week Results from Phase 3 Study of Fezolinetant for the Nonhormonal Treatment of Vasomotor Symptoms in Women in Asia

Astellas' MOONLIGHT 1™ clinical trial evaluating investigational fezolinetant 30 mg administered once daily

TOKYO, March 15, 2022 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced topline results from the ongoing Phase 3 MOONLIGHT 1™ clinical trial investigating the efficacy and safety of fezolinetant, an investigational oral, nonhormonal compound being studied for the treatment of moderate to severe vasomotor symptoms associated with menopause (VMS), in women in Asia. VMS, characterized by hot flashes (also called hot flushes) and/or night sweats, are common symptoms of menopause.[1,2]

Based on the 12-week data analysis in 302 participants, fezolinetant 30 mg once daily (QD) in women in China, Korea and Taiwan did not meet the pre-defined endpoints for efficacy. While numerical improvements from baseline were observed in the fezolinetant 30 mg treatment group, the results did not meet statistical significance. The 12-week safety data in this study are aligned with what was previously observed with fezolinetant. Detailed results will be submitted for publication following completion of the 24-week analyses.

"We are evaluating the results and look forward to reviewing the full data set once the study is complete," said Nancy Martin, M.D., PharmD, Vice President, Global Medical Head, Medical Specialties, Astellas.

MOONLIGHT 1 is an ongoing randomized Phase 3 clinical trial evaluating the efficacy and safety of fezolinetant in 302 women in China, Korea and Taiwan who take fezolinetant 30 mg QD for 24 weeks. The trial is double-blinded and placebo-controlled for the first 12 weeks, followed by a 12-week non-controlled extension treatment period. Specifically, the MOONLIGHT 1 study is being conducted to support registration in China, Korea and Taiwan. As previously reported, the results from two pivotal Phase 3 clinical trials, SKYLIGHT 1™ and SKYLIGHT 2™, along with the findings from the long-term safety study, SKYLIGHT 4™, will provide the foundational data for regulatory submissions in the U.S. and Europe.

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

This result will have no impact on the financial forecasts of the current fiscal year ending March 31, 2022.

About MOONLIGHT Phase 3 Clinical Trials
The MOONLIGHT 1™ clinical trial (NCT04234204) remains ongoing and has enrolled 302 women in China, Korea and Taiwan with moderate to severe VMS associated with menopause. The trial is double-blinded and placebo-controlled for the first 12 weeks, followed by a 12-week non-controlled extension treatment period. There were nearly 60 sites across Asia. MOONLIGHT 3™ (NCT04451226) is an ongoing 52-week single-arm Phase 3 clinical trial designed to investigate the long-term safety of fezolinetant in women in China with VMS associated with menopause. 150 women were enrolled at 34 sites in China.

About BRIGHT SKY™ Phase 3 Program
The BRIGHT SKY pivotal trials, SKYLIGHT 1™ (NCT04003155) and SKYLIGHT 2™ (NCT04003142), enrolled over 1,020 women with moderate to severe VMS. The trials are double-blinded and placebo-controlled for the first 12 weeks followed by a 40-week active treatment extension period. Women were enrolled at over 280 sites within the U.S., Canada and Europe. SKYLIGHT 4™ (NCT04003389) is a 52-week double-blinded and placebo-controlled study designed to investigate 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] Worldwide, more than 50% of women 40 to 64 years of age experience VMS and, in East Asia, the prevalence of VMS has been estimated to be around 80% of women 40 to 65 years of age, with 55% having moderate to severe VMS.[3,4] 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.[5,6,7] 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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