Press Release

Astellas Announces Topline Results from Phase 3 Long-Term Safety Study of Fezolinetant in Mainland China

Clinical trial evaluated the safety and tolerability of 30 mg dose for the treatment of vasomotor symptoms (VMS) associated with menopause

TOKYO, September 5, 2022 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced topline results from the Phase 3 MOONLIGHT 3™ clinical trial in women in mainland China evaluating the long-term safety and tolerability of fezolinetant, an investigational oral, nonhormonal compound being studied 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]

MOONLIGHT 3 is a 52-week single-arm Phase 3 clinical trial investigating the long-term safety and tolerability of fezolinetant 30 mg taken once daily in 150 women in mainland China seeking treatment for relief of VMS associated with menopause. The study's primary endpoint is the frequency and severity of adverse events (AEs), which were generally consistent with previous Phase 3 studies of fezolinetant. Detailed results will be submitted for publication in the near future.

"The topline results from the MOONLIGHT 3 study are very encouraging and, upon initial review, further support the long-term safety of fezolinetant," said Ahsan Arozullah, M.D., M.P.H., Senior Vice President and Head of Development Therapeutic Areas, Astellas. "We are evaluating the full MOONLIGHT data sets and remain committed to developing innovative treatments in this therapeutic area with the hope of delivering a first-in-class, nonhormonal treatment option for women with moderate to severe VMS."

Fezolinetant is an investigational selective neurokinin-3 (NK3) receptor antagonist and is not approved anywhere in the world. In the U.S., a New Drug Application for fezolinetant for the treatment of moderate to severe VMS associated with menopause is under review. The NDA submission is based on results from two pivotal Phase 3 clinical trials, SKYLIGHT 1™ and SKYLIGHT 2™, and the Phase 3 long-term safety study, SKYLIGHT 4™.

This result will have no impact on the financial forecasts of the current fiscal year ending March 31, 2023.

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

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] 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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