Press Release

Astellas to Present Fezolinetant 12-Week Findings from Phase 3 SKYLIGHT 2™ Trial in Oral Session at The North American Menopause Society 2021 Annual Meeting

Astellas' investigational non-hormonal treatment demonstrates reduction in frequency and severity of moderate to severe vasomotor symptoms (VMS) associated with menopause

TOKYO, September 22, 2021 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") will present 12-week results (S-13) from the pivotal Phase 3 SKYLIGHT 2™ clinical trial of fezolinetant for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause on Friday, September 24, 2021 during the Top-Scoring Abstract Presentations at The North American Menopause Society 2021 Annual Meeting in Washington, D.C. VMS, characterized by hot flashes (also called hot flushes) and/or night sweats, are common symptoms of menopause.[1]

Findings showed fezolinetant 30 and 45 mg administered once-daily met the co-primary endpoints of the study, demonstrating a statistically significant reduction from baseline in the frequency and severity of moderate to severe VMS at weeks 4 and 12 versus placebo. Results also showed that improvement in VMS frequency and severity greater than placebo was observed through the 12-week placebo-controlled period, with improvement observed as early as one week after treatment onset for both doses.

Fezolinetant is an investigational, non-hormonal selective neurokinin-3 receptor (NK3R) antagonist that blocks a specific receptor in the temperature control center of the brain (the hypothalamus) to reduce the frequency and severity of VMS associated with menopause.[2,3,4,5]

"VMS are the most common menopausal symptoms for which women seek treatment, yet there have been limited non-hormonal options available to women and healthcare providers," said Dr. Nanette Santoro, M.D., Professor and Chair, University of Colorado School of Medicine. "These results from the SKYLIGHT 2 study show that fezolinetant has the potential to help reduce frequency and severity of moderate to severe VMS."

For the co-primary endpoint of reduction in mean frequency of moderate to severe VMS versus placebo, fezolinetant 30 mg demonstrated a -1.82 (p=<0.001) and -1.86 (p=<0.001) mean change per day at weeks 4 and 12, respectively. At the 45 mg dose, fezolinetant showed a -2.55 (p=<0.001) and -2.53 (p=<0.001) mean change per day in VMS frequency versus placebo at weeks 4 and 12, respectively.

Additionally, for the co-primary endpoint of reduction in mean severity of moderate to severe VMS versus placebo, fezolinetant 30 mg demonstrated a -0.15 (p=<0.021) and -0.16 (p=0.049) mean change per day at weeks 4 and 12, respectively. The 45 mg dose of fezolinetant showed a -0.29 (p=<0.001) mean change in severity per day versus placebo at both weeks 4 and 12.

Treatment emergent adverse events (TEAE) were reported by 40 percent, 36 percent and 32 percent of individuals in the SKYLIGHT 2 trial in the 30 mg, 45 mg and placebo groups, respectively. Headache was the most common TEAE in the fezolinetant groups and was reported by 3 percent, 4 percent and 2 percent in the 30 mg, 45 mg and placebo groups, respectively. Serious TEAEs occurred in less than 2 percent of patients in the fezolinetant groups and there were no drug-related serious TEAEs. Detailed safety results will be available following the completion of the fezolinetant Phase 3 program, which will also include the SKYLIGHT 1™ and SKYLIGHT 4™ studies.

“As we work to advance the development of an NK3R targeted treatment for VMS associated with menopause, we are encouraged by the 12-week results of the SKYLIGHT 2 study,” said Andrew Krivoshik, Senior Vice President and Head of Development Therapeutic Areas, Astellas. “We look forward to continuing to progress our Phase 3 development program and potentially introducing a first-in-class, non-hormonal treatment option for moderate to severe vasomotor symptoms associated with menopause.”

About BRIGHT SKY™ Phase 3 Program

The BRIGHT SKY pivotal trials, SKYLIGHT 1™ (NCT04003155) and SKYLIGHT 2™ (NCT04003142), 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 over 280 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 over 200 sites within the US, Canada and Europe.

About Vasomotor Symptoms Associated with Menopause (VMS)

Vasomotor symptoms (VMS), characterized by hot flashes (also called hot flushes) and/or night sweats are common symptoms of menopause.[1] Worldwide, more than half of women 40 to 64 years of age experience VMS and, in the United States, about 60% to 80% of women experience these symptoms during or after the menopausal transition.[6,7,8,9] VMS can have a disruptive impact on women’s daily activities and overall quality of life.[1]

About Fezolinetant

Fezolinetant is an oral non-hormonal therapy in clinical development for the treatment of moderate to severe vasomotor symptoms (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 VMS associated with menopause.[3,4,5]

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.

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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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