Press Release

Astellas Initiates Phase 3 Clinical Trials for Fezolinetant in Postmenopausal Women with Vasomotor Symptoms

TOKYO, August 6, 2019 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced dosing of the first patient in the SKYLIGHT 1™ Phase 3 pivotal trial for fezolinetant, an investigational oral, non-hormonal compound being studied for the treatment of moderate-to-severe vasomotor symptoms (VMS) – i.e., hot flashes and night sweats associated with menopause. Fezolinetant is a selective neurokinin-3 (NK3) receptor antagonist. The first trials of the BRIGHT SKY™ clinical development program will evaluate the efficacy and safety of 30 and 45 mg once-daily (QD) fezolinetant in reducing VMS frequency and severity.

"There are currently limited non-hormonal options for managing vasomotor symptoms, which can be quite disruptive and often interfere with daily life," said Salim Mujais, M.D., Senior Vice President and Therapeutic Area Head, Medical Specialties, Astellas. "With the initiation of our Phase 3 fezolinetant program, we move further towards our goal of providing women with a non-hormonal treatment for moderate-to-severe hot flashes."

Results of a Phase 2b fezolinetant study were presented at The Endocrine Society's annual meeting in March 2019. Additional information on the Phase 2b study results can be found here.

About the Phase 3 Program
The global BRIGHT SKY program will launch with three Phase 3 clinical trials (SKYLIGHT 1™, SKYLIGHT 2™ and SKYLIGHT 4™) that will enroll postmenopausal women with VMS. The program will evaluate the efficacy and safety of fezolinetant 30 or 45 mg QD.

The BRIGHT SKY pivotal trials, SKYLIGHT 1 and SKYLIGHT 2, will each enroll approximately 450 women with moderate-to-severe VMS and will be double-blinded and placebo-controlled for the first 12 weeks followed by non-controlled 40-week extension periods. For each pivotal trial, women will be enrolled at approximately 200 sites within the US, Canada and Europe. SKYLIGHT 4 is a 52-week double-blinded and placebo-controlled study to investigate long-term safety. For SKYLIGHT 4, about 1,150 women with VMS will be enrolled at approximately 250 sites within the US, Canada and Europe.

For more information about the Phase 3 fezolinetant trials, please visit http://www.clinicaltrials.gov, trial identifiers NCT04003155, NCT04003142 and NCT04003389.

About Fezolinetant
Fezolinetant is an investigational oral, non-hormonal compound being developed for the potential treatment of moderate-to-severe VMS, including hot flashes and night sweats. Fezolinetant works by blocking neurokinin B (NKB) signaling and normalizing KNDy (kisspeptin/NKB/dynorphin) neuron activity, which modulates the temperature control center and reduces the frequency and severity of hot flashes.

About Vasomotor Symptoms (VMS)
Globally, approximately 57 percent of women 40 to 64 years of age have reported the occurrence of hot flashes (also known as hot flushes) and sweating.[1] VMS can have a considerable effect on women's comfort and sleep and can lead to anxiety, irritability, loss of productivity and depression.[2] Hot flashes are also the most common symptom for women transitioning through menopause.[3]

About Astellas
Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. 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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