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ASIA EDITION

Astellas Initiates Phase 3 Clinical Trials for Fezolinetant

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In Postmenopausal Women with Vasomotor Symptoms

Japan based Astellas Pharma Inc. has 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.”

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,Canadaand 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.