BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Astellas' menopause drug fails in Asia trial

16 March 2022 | News

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

Japan-based Astellas Pharma Inc. has 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.

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.

.