Phase 3 study finds fezolinetant reduces the frequency and severity of menopausal hot flashes

June 11 2022

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Fezolinetant significantly reduced the frequency and severity of moderate-to-severe vasomotor symptoms (VMS), or hot flashes,

associated with menopause, according to a Phase 3 industry-sponsored study being presented Saturday at ENDO 2022, the Endocrine Society's annual meeting in Atlanta, Ga.

The SKYLIGHT 2 trial was a 52-week study to investigate the safety and efficacy of fezolinetant (a neurokinin 3 receptor antagonist) on the frequency and severity of moderate-to-severe VMS and sleep disturbance. The mean change in patient-reported sleep disturbance, from baseline to week 12, was a key secondary endpoint in the study.

"VMS associated with menopause, which are characterized by hot flashes and/or night sweats, affect millions of women worldwide and can impact daily activities and quality of life," said Genevieve Neal-Perry, M.D, Ph.D., Distinguished Professor and Chair of Obstetrics and Gynecology at the University of North Carolina School of Medicine in Chapel Hill, N.C.

The double-blind Phase 3 study randomized 501 post-menopausal women ages 40–65 with an average of seven or more moderate-to-severe hot flashes/day to placebo or one of two once-daily doses of fezolinetant—30mg or 45mg—for 12 weeks. In the extension period, those on placebo were re-randomized to fezolinetant 30mg or 45mg, and those originally on fezolinetant remained on their dose for the remaining 40 weeks. The extension period analysis comprised 484 women.

Neal-Perry and colleagues evaluated the efficacy of fezolinetant compared to placebo and found improvement in VMS frequency and severity through week 12. Both doses were associated with a statistically significant reduction in the frequency and severity of hot flashes, which was maintained through the 52-week study period. Data support the overall safety and tolerability previously observed for fezolinetant at the 30 and 45 mg doses.

Those who were re-randomized from placebo to fezolinetant experienced a reduction in frequency and severity of VMS consistent with the women initially randomized to fezolinetant. The treatment also reduced sleep disturbances as assessed by Patient-Reported Outcomes Measurement Information System Sleep Disturbance (PROMIS SD SF 8b).

"These results, along with other fezolinetant studies, will be important in understanding the use of this oral nonhormonal selective NK3 receptor antagonist to treat moderate-to-severe VMS associated with menopause," Neal-Perry said.

More information: Neal-Perry will speak at the Endocrine Society's reproductive health news conference on Monday, June 13 at 9 AM.

Provided by The Endocrine Society