

Bionovo reports encouraging data for menopause drug

By Sarah Routledge

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Bionovo has announced that its lead candidate, MF101, showed positive phase II results for the treatment of hot flashes associated with menopause.

The phase II trial enrolled 217 women, randomized into three treatment groups receiving MF101 (5 grams/day), MF101 (10 grams/day), or placebo for twelve weeks. Bionovo's primary objectives in the study were to assess the safety, tolerability and the potential efficacy of two doses of MF101 to reduce the frequency and severity of hot flashes.

Both doses of MF101 were more effective than placebo at reducing the frequency and severity of hot flashes from the start of the trial until the end of the treatment period 12 weeks later. There was a dose response trend suggesting that the higher dose of MF101 was more effective at reducing both frequency and severity of hot flashes than the lower dose.

MF101 is a novel estrogen receptor beta agonist that is expected not to stimulate the endometrium or breast tissue. Safety analyses showed no cases of endometrial hyperplasia or uterine cancer during the trial and there were no differences in incidence of vaginal bleeding between the placebo group and the two cohorts treated with MF101. The only side effect that increased with MF101 treatment was loose stool/diarrhea (12% in each of the drug arms vs. 3% in placebo arm).

"Recent clinical trials, such as the HERS and the WHI, elucidated important safety concerns of postmenopausal hormone therapy and resulted in significantly fewer women using these products," said Isaac Cohen, CEO of Bionovo. "For this reason, it is important for us to find safer alternatives for treating menopausal symptoms."