REPRODUCTIVE ENDOCRINOLOGY

Elagolix in endometriosis

Effective treatment options for pain management in women with endometriosis are currently limited. Following promising phase II data, results from two phase III trials now show that elagolix — an oral gonadotropin-releasing hormone (GnRH) receptor antagonist that suppresses oestrogen production reduces pain symptoms in women with endometriosis-related pain.

Investigators performed two similar randomized phase III trials, Elaris Endometriosis I (EM-I) and EM-II, to evaluate the efficacy and safety of 6 months of treatment with low-dose (150 mg; once daily) and high-dose (200 mg; twice daily) elagolix, compared with placebo, in women with moderate or severe endometriosis-associated pain. The two primary efficacy end points were the proportion of women who had a clinical response with respect to dysmenorrhoea and non-menstrual pelvic pain at 3 months, which were each measured as a reduction in pain scores and a decreased or stable use of rescue analgesic agents.

Compared with placebo, significantly more women who received low or high doses of elagolix met the clinical response criteria with respect to both primary end points at 3 months in Elaris EM-1 (P < 0.001 for all comparisons) and EM-II ($P \le 0.003$ for all comparisons). In both trials, these clinical responses were sustained at 6 months. Compared with placebo, patients who received elagolix had more hypo-oestrogenic symptoms, including a higher incidence of hot flushes (nonsevere), increased serum levels of lipids and reduced bone mineral density. No adverse endometrial effects were reported with elagolix treatment.

Overall, the study shows the dose-dependent superiority of elagolix compared with placebo in reducing two hallmark symptoms of endometriosis-related pain. "These results highlight the efficacy and safety profile of elagolix and demonstrate its potential to be an important treatment option for women suffering from endometriosis," concludes lead investigator Hugh Taylor.

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