AN ORAL GNRH ANTAGONIST, ELAGOLIX, REDUCES ENDOMETRIOSIS-ASSOCIATED PAIN: RESULTS OF A 24-WEEK RANDOMIZED STUDY

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Objective: To evaluate efficacy and safety of elagolix, a novel oral GnRH antagonist, for treatment of endometriosis-associated pain, at a dose that partially suppresses E2 levels.

Methods: A Phase 2, randomized, double-blind, placebo-controlled study of women with surgically confirmed endometriosis, and moderate or severe dysmenorrhea and nonmenstrual pelvic pain (NMPP), who received elagolix 150mg q.d. (n=66) or placebo (n=66) for 8 weeks followed by 16 weeks of open-label elagolix 150mg. Dysmenorrhea, NMPP, dyspareunia and analgesic use were recorded daily.

Results: For all assessments, average reduction from baseline to week 8 was significantly greater with elagolix versus placebo (dysmenorrhea -1.1 vs -0.4, NMPP -0.5 vs -0.2, dyspareunia -0.6 vs -0.2, percent days with analgesic use -21.6% vs. -9.2%, p<0.01 for all). Additional improvements were observed for elagolix patients during the open-label period; patients initially randomized to placebo had comparable improvements by week 24 (dysmenorrhea -1.4 and -1.3, NMPP -0.8 and -0.5, dyspareunia -0.8 and -0.6, percent days with analgesic use -29.2% and -20.6%; elagolix and placebo, respectively). Quality of life (QoL, EHP-5) and patient’s global impression of change (PGIC) were significantly improved with elagolix. Over 24-weeks, the most common adverse events in elagolix patients were nausea, headache, and hot flush, which occurred in 9.9% of patients each.

Conclusions: Elagolix was well-tolerated and resulted in consistent, sustained reduction in dysmenorrhea, NMPP, and dyspareunia and improvements in QoL and PGIC in women with endometriosis-associated pelvic pain.

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