Generic Name:
Elagolix
Trade Name:
Orilissa
Company:
Abbvie
Notes:

Abbvie announced FDA approval of elagolix, the first and only oral gonadotropin-releasing hormone (GnRH) antagonist specifically developed for women with moderate to severe endometriosis pain?and the first FDA-approved oral treatment for this condition in more than a decade.

Endometriosis-associated pain is often managed with medications such as oral contraceptives, NSAIDs, opioids, and hormonal therapies. These treatments can work for some women, but very few are specifically indicated for treatment of endometriosis. In more extensive cases of the disease, surgical interventions (e.g., laparotomy, laparoscopy, or hysterectomy) are often pursued and may not be curative for all individuals.

Approval was supported by data from two replicate studies in the largest endometriosis Phase III study program conducted to date, which evaluated nearly 1,700 women with moderate to severe endometriosis pain.

Clinical trial data demonstrated that elagolix significantly reduced the three most common types of endometriosis pain: daily menstrual pelvic pain, nonmenstrual pelvic pain, and pain with sex. A higher proportion of women treated with elagolix 150 mg once daily and 200 mg twice daily were responders for daily menstrual pain and nonmenstrual pelvic pain compared with placebo in a dose-dependent manner at month three. Women were defined as responders if they experienced a reduction in daily menstrual pain and nonmenstrual pelvic pain with no increase in analgesic use (NSAID or opioid) for endometriosis-associated pain.

Both elagolix treatment groups showed statistically significant greater mean decreases from baseline compared with placebo in daily menstrual pain and nonmenstrual pelvic pain at month six. Women in the Phase III studies also provided a daily self-assessment of their endometriosis pain using a numeric rating scale (NRS). Women taking elagolix 150 mg once daily and 200 mg twice daily reported a statistically ($P < 0.001$) significant reduction from baseline in NRS scores compared with placebo at month three.

Data also demonstrated that women taking elagolix 200 mg twice daily showed statistically significant greater reduction in pain with sex from baseline to month three compared with placebo.

The recommended duration of use for elagolix is up to 24 months for the 150 mg once daily dose and up to 6 months for the 200 mg twice daily dose, as it causes a dose-dependent decrease in bone mineral density (BMD). BMD loss is greater with increasing duration of use and may not be completely reversible after stopping treatment.

For women with moderate hepatic impairment, the recommended dosage is 150 mg once daily for up to 6 months.

Elagolix is recommended to be taken orally at approximately the same time each day, with or without food. The new agent is expected to be available in U.S. pharmacies in early August 2018.

Medication Monitor Categories:

New Drug Approvals
