Orilissa™ (elagolix) – New drug approval

- On July 24, 2018, AbbVie announced the FDA approval of Orilissa (elagolix), for the management of moderate to severe pain associated with endometriosis.

- According to the National Institute of Child Health and Human Development, endometriosis is one of the most common gynecologic disorders, affecting more than 5.5 million women in North America. Common symptoms of endometriosis include painful menstrual cramps, chronic pelvic pain, intestinal pain, pain during or after sex, and infertility.

- Orilissa is an oral gonadotropin-releasing hormone receptor antagonist that suppresses luteinizing hormone and follicle-stimulating hormone, leading to decreased blood concentrations of the ovarian sex hormones, estradiol and progesterone.

- The safety and efficacy of Orilissa were demonstrated in two placebo-controlled studies in 1,686 premenopausal women with moderate to severe endometriosis pain. Patients were randomized to receive Orilissa 150 mg once daily, Orilissa 200 mg twice daily, or placebo. The primary endpoints were the proportion of patients whose dysmenorrhea responded to treatment at month 3 and the proportion of patients whose non-menstrual pelvic pain responded to treatment at month 3.

    — In both studies, a higher proportion of women treated with Orilissa were responders for dysmenorrhea and non-menstrual pelvic pain vs. placebo in a dose-dependent manner at month 3 ($p \leq 0.001$ for all comparisons except non-menstrual pelvic pain with Orilissa 150 mg once daily in study 2, $p \leq 0.01$).

- Orilissa is contraindicated in women who are pregnant, have known osteoporosis, severe hepatic impairment, and with concomitant use of strong organic anion transporting polypeptide 1B1 inhibitors.

- Warnings and precautions of Orilissa include bone loss; change in menstrual bleeding pattern and reduced ability to recognize pregnancy; suicidal ideation, suicidal behavior, and exacerbation of mood disorders; hepatic transaminase elevations; and reduced efficacy with estrogen-containing contraceptives.

- The most common adverse reactions (> 5%) with Orilissa use were hot flushes and night sweats, headache, nausea, insomnia, amenorrhea, anxiety, arthralgia, depression-related adverse reactions and mood changes.

- The recommended dose of Orilissa is based on coexisting conditions as follows:

Dosage regimen	Maximum treatment duration	Coexisting condition
150 mg once daily	24 months	None
200 mg twice daily	6 months	Dyspareunia
150 mg once daily. Use of 200 mg twice daily is not recommended.	6 months	Moderate hepatic impairment (Child-Pugh Class B)

    — Exclude pregnancy before starting Orilissa or start Orilissa within 7 days from the onset of menses.

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    - — Use the lowest effective dose, taking into account the severity of symptoms and treatment objectives.
    - — Limit the duration of use because of bone loss.

- AbbVie plans to launch Orilissa in early August 2018. Orilissa will be available as 150 mg and 200 mg capsules.