FDA Approves First Oral Hormone Therapy for Treating Advanced Prostate Cancer

Orgovyx (relugolix) may eliminate some patients' need to visit a clinic for treatments administered by a health care provider.

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Today [December 18, 2020], the U.S. Food and Drug Administration approved Orgovyx (relugolix) for the treatment of adult patients with advanced prostate cancer.

"Today's approval marks the first oral drug in this class and it may eliminate some patients' need to visit the clinic for treatments that require administration by a health care provider," said Richard Pazdur, MD, director of the FDA's Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the FDA's Center for Drug Evaluation and Research. "This potential to reduce clinic visits can be especially beneficial in helping patients with cancer stay home and avoid exposure during the coronavirus pandemic."

The American Cancer Society estimates that in 2020, there will have been more than 190,000 cases of prostate cancer in the U.S. One of the treatment options for advanced prostate cancer is androgen deprivation therapy, which uses drugs to lower levels of the hormones that help prostate cancer cells grow. Current FDA-approved treatments of this type are injected or placed as small implants under the skin. Orgovyx is an orally administered treatment that works by blocking the pituitary gland from making hormones called luteinizing hormone and follicle-stimulating hormone, thereby reducing the amount of testosterone the testicles are able to make.

The safety and efficacy of Orgovyx was evaluated in a randomized, open-label trial in men with advanced prostate cancer. The patients randomly received either Orgovyx once daily or injections of leuprolide, another hormone-targeting drug, every three months for 48 weeks. The objective was to determine if Orgovyx achieved and maintained low enough levels of testosterone (castrate levels), by day 29 through end of the treatment course. In the 622 patients who received Orgovyx, the castration rate was 96.7%.

The most common side effects of Orgovyx include: hot flush, increased glucose, increased triglycerides, musculoskeletal pain, decreased hemoglobin, fatigue, constipation, diarrhea and increased levels of certain liver enzymes. Androgen deprivation therapies such as Orgovyx may

affect the heart’s electrical properties or cause electrolyte abnormalities, therefore healthcare providers should consider periodic monitoring of electrocardiograms and electrolytes. Based on findings in animals and the mechanism of action, Orgovyx can cause fetal harm and loss of pregnancy when administered to a pregnant female; it is advised that males with female partners of reproductive potential use effective contraception during treatment and for two weeks after the last dose of Orgovyx.

Due to the drug’s suppression of the pituitary gonadal system, diagnostic test results of the pituitary gonadotropic and gonadal functions conducted during and after taking Orgovyx may be affected.

The FDA granted approval of Orgovyx to Myovant Sciences.

This news release was originally published on the Food and Drug Administration website on December 18, 2020.
