Orgovyx™ (relugolix) – New drug approval

- On December 18, 2020, the FDA announced the approval of Myovant Sciences' Orgovyx (relugolix), for the treatment of adult patients with advanced prostate cancer.

- The American Cancer Society estimates that in 2020, there will have been more than 190,000 cases of prostate cancer in the U.S. Androgen deprivation therapy (eg, gonadotropin-releasing hormone [GnRH] receptor antagonists) is a commonly used treatment option for patients with advanced prostate cancer. Previously approved treatments of this type were injected or placed as small implants under the skin.

    — Orgovyx is the first oral GnRH receptor antagonist approved for prostate cancer.

- The efficacy of Orgovyx was established in the HERO trial, a randomized, open-label study in 934 men with advanced prostate cancer. Patients received Orgovyx orally once daily or leuprolide injection (eg, Lupron Depot®) subcutaneously every 3 months. The major efficacy outcome measure was medical castration rate defined as achieving and maintaining serum testosterone suppression to castrate levels (< 50 ng/dL) by day 29 through 48 weeks of treatment.

    — Medical castration was achieved in 96.7% (95% CI: 94.9, 97.9) of patients treated with Orgovyx vs. 88.8% (95% CI: 84.6, 91.8) with leuprolide.

- Warnings and precautions for Orgovyx include QT/QTc interval prolongation, embryo-fetal toxicity, and laboratory testing.

- The most common adverse reactions (≥ 10%) and laboratory abnormalities (≥ 15%) with Orgovyx use were hot flush, glucose increased, triglycerides increased, musculoskeletal pain, hemoglobin decreased, alanine aminotransferase (ALT) increased, fatigue, aspartate aminotransferase (AST) increased, constipation, and diarrhea.

- Treatment of Orgovyx should be initiated with a loading dose of 360 mg on the first day and treatment should be continued with a 120 mg dose taken orally once daily at approximately the same time each day.

    — If treatment with Orgovyx is interrupted for greater than 7 days, Orgovyx should be restarted with a loading dose of 360 mg on the first day and then continued with a dose of 120 mg once daily.
    — In patients treated with GnRH receptor agonists and antagonists for prostate cancer, treatment is usually continued upon development of nonmetastatic or metastatic castration-resistant prostate cancer.

- Myovant Sciences' launch plans for Orgovyx are pending. Orgovyx will be available as a 120 mg tablet.