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Clinical Update

Relugolix Receives FDA Approval for Advanced Prostate Cancer

On December 18, 2020, the U.S. Food and Drug Administration (FDA) approved Orgovyx™ (relugolix) tablets as the first oral treatment option for adults with advanced prostate cancer. Prostate cancer is classified as Stage IV, or advanced, when the disease spreads to regions outside of the prostate, such as the lungs, liver, or brain, and/or returns after initial treatment. The treatment goal for patients diagnosed with advanced prostate cancer is to reduce the size of the tumor(s) and control symptoms. Orgovyx™ works by preventing gonadotropin-releasing hormone (GnRH) from binding to its receptors, which results in the shutting down of the body's natural testosterone production. Testosterone levels will eventually decrease to "castrate levels," more than 80% below normal levels, which in turn stops the growth of cancer cells and reduces tumor size. This approval comes after results from the HERO study, which involved 934 men with advanced prostate cancer who were randomized to two different treatment groups. One treatment arm received a loading dose of Orgovyx™ followed by a maintenance daily dose, while the other group received a current standard of therapy for prostate cancer, leuprolide acetate, injected once every three months for a total treatment duration of 48 weeks. Results showed that men with advanced prostate cancer who received Orgovyx™ achieved and maintained adequate serum testosterone suppression, with 96.7% of patients who received Orgovyx™ reaching castrate levels of testosterone by day 29 versus 88.8% in the leuprolide acetate treatment group. Orgovyx™ not only provides patients with advanced prostate cancer an alternative to injectable treatment, but also eliminates the need to visit clinics for treatments that may require assistance from a health care provider, reducing any potential exposure during the coronavirus pandemic. Orgovyx™ is anticipated to be available this month.

Safety First

AvKARE Issues a Voluntary Recall for Sildenafil and Trazodone Tablets

On December 9, 2020, the FDA announced a voluntary recall issued by AvKARE for certain lot numbers of sildenafil 100 mg tablets and trazodone 100 mg tablets. These specific batches are being recalled due to a product mix-up in which both drugs were inadvertently packaged together. Unintentional consumption of either medication may result in adverse effects. Sildenafil is the active ingredient found in both Viagra, which used to treat erectile dysfunction, as well as Revatio, which is indicated to treat high blood pressure in the arteries of the lungs. Consumption of sildenafil can be harmful when used in combination with certain blood pressure and heart medications and may trigger dangerously low blood pressure and light headedness. Trazodone is a medication commonly used to treat major depressive disorder and inadvertent use may cause side effects such as sedation, dizziness and blurred vision. AvKARE has arranged for distributors and customers to return all recalled products. Questions regarding the recall can be addressed directly to AvKARE by phone or email. Adverse reactions or quality problems can be reported to the FDA's MedWatch Adverse Event Reporting program. To date, no adverse events related to the recall have been reported to the manufacturer.

From the Industry

Faricimab Meets Primary Endpoint in Diabetic Macular Edema Studies

On December 21, 2020, Roche announced that their investigational drug, faricimab, met its primary endpoint showing non-inferiority in improvement in clarity of vision when compared to aflibercept in patients with diabetic macular edema (DME). DME, which affects about 21 million people worldwide, is a complication of diabetic retinopathy that occurs when high levels of sugar circulating in the blood damages blood vessels within the eye. The resulting swelling and blockage of blood supply to the retina can cause severe vision-loss or even blindness. Faricimab, which is injected directly into the eye, works to stabilize blood vessels by targeting two of the driving pathways for retinal complications: angiopoietin-2 (ANG-2) and vascular endothelial growth factor-A (VEGF-A). Two main studies, YOSEMITE and RHINE, were conducted in which patients with DME were randomized into three groups receiving either faricimab or aflibercept at fixed eight-week intervals, or faricimab at personalized intervals of up to 16 weeks, following a loading phase. More than half of participants in the faricimab personalized dosing group achieved efficacy with an extended time between treatments of 16 weeks compared to aflibercept, which is commonly administered every 4-8 weeks. These results show the potential faricimab has in offering patients with DME lasting vision improvements and lowering treatment burden.

FDA Approvals

Recent FDA Approvals

Novel Drug Approval: Orgovyx™ (relugolix)
Oral tablet approved for the treatment of adult patients with advanced prostate cancer
[12/18/20 – Priority Review – MYOVANT SCIENCES GMBH]

Novel Drug Approval: Gemtesa®(vibegron)
Oral tablet approved for the treatment of adult patients with overactive bladder (OAB) experiencing symptoms of urge urinary incontinence, frequency, and urgency [12/23/20 – UROVANT SCIENCES GMBH]

New Generics

New Generics Entering the Marketplace

Zytiga® (abiraterone)
Indication: Metastatic prostate cancer
Dosage Form/Strength: 500 MG Oral tablets
Average Wholesale Price (AWP): Generic = $11,745 | Brand = $13,064

Vivlodex® (meloxicam)
Indication: Management of osteoarthritis (OA) pain
Dosage Form/Strength: 5 and 10 MG Oral capsules
Average Wholesale Price (AWP):
Generic = $1,863 | Brand = $2,070

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