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Clinical Update

Allergan Submits New Drug Application for Treatment of a Common Age-Related Eye Condition

On February 25, 2021, Allergan announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the investigational drug AGN-190584, more commonly known as pilocarpine 1.25% ophthalmic solution, for the treatment of presbyopia. Presbyopia, the natural age-related loss of the eyes' ability to focus on close-up objects, affects approximately 128 million people across the U.S., or about half of the adult population. This condition typically occurs in adults over the age of 40 years. Symptoms, such as blurred vision up close, eyestrain or headaches, occur as a result of the hardening of the lens of the eye, preventing it from changing shape to focus on close-up images. Although the onset and progression of presbyopia cannot be prevented, options do exist to help alleviate signs and symptoms, including glasses, contact lenses and certain surgeries. Pilocarpine 1.25% is a once daily eye drop that may serve as a new alternative treatment for patients who prefer not to wear eyewear or do not wish to undergo invasive surgical procedures. It works by contracting the eye muscles, which constricts the pupil and enhances the depth of focus while still allowing some pupil response to light, which is important in protecting the eye from damage from bright lights. Pilocarpine eye drops have previously been approved to treat various conditions associated with the eye such as glaucoma and elevated fluid pressure within the eye. Allergan's NDA was submitted after data from two Phase 3 trials, GEMINI 1 and GEMINI 2, showed a favorable efficacy and safety profile for pilocarpine 1.25%. When compared to placebo, pilocarpine 1.25% showed an improvement in near vision in low-light conditions without sacrificing distance vision. There were no serious adverse events observed within the trial, with headache being among the most common. If approved, this medication would provide a non-surgical alternative for individuals with presbyopia seeking an improvement in their reading vision.

Drug Safety

Nationwide Recall of Spironolactone Tablets Due to Mislabeling

On March 9, 2021, the FDA announced a voluntary recall of spironolactone tablets manufactured by Bryant Ranch Prepack. The recall was issued as a result of a labeling error in which certain lots of spironolactone 50 mg were labeled as 25 mg tablets and vice versa. Spironolactone belongs to a class of medications known as aldosterone antagonists, which work by helping the kidneys produce more urine, thereby decreasing excess fluids in the body. It is approved to treat a variety of conditions including heart failure, edema (fluid retention), and as an add-on therapy for patients with uncontrolled high blood pressure. A sudden change in the dose of spironolactone may cause fluctuations in potassium levels which may lead to abnormal heart rhythms. Other potential side effects from a change in the dose of spironolactone include elevation, or drop, in blood pressure as well as fluctuations in body weight caused by edema. Patients are advised to contact their health care provider if they have experienced any complications related to taking this drug. The manufacturer has arranged for the return of all recalled products from both distributors and impacted patients. As of March 9, the manufacturer had not received any reports of adverse reactions reported to their company or the FDA's MedWatch Adverse Event Reporting Program.

From the Industry

FDA Approves Fotivda® (tivozanib) for Renal Cell Carcinoma

On March 10, 2021, the FDA approved AVEO Oncology's Fotivda® (tivozanib) for the treatment of adult patients with advanced relapsed or refractory renal cell carcinoma (RCC). RCC is the most common type of kidney cancer and typically occurs as a single tumor within a kidney but may also occur in both kidneys or spread to other organs such as the liver, lungs or brain. Traditional treatment options for individuals with renal cell carcinoma include surgery, radiation therapy, chemotherapy, immunotherapy, and other targeted therapies. Patients with this disease may relapse, with disease re-emerging sometimes years after initial treatment. Fotivda® works by targeting and selectively inhibiting vascular endothelia growth factor (VEGF) receptors and other enzymes thought to contribute to cell growth and survival. VEGF binds to VEGF receptors and promotes angiogenesis, a process by which new blood vessels form, thereby carrying oxygen and nutrients to stimulate the growth of cells. In cancer patients, VEGF signaling has been shown to enable tumors and cancerous cells to grow and survive. This approval comes after results from a Phase 3 study, TIVO-3, which showed that tivozanib was superior to sorafenib – another chemotherapy drug – in producing progression-free survival (PFS) in individuals with relapsed or refractory advanced RCC following two or more prior therapies. Median PFS in the tivozanib group was 5.6 months compared to 3.9 months in the sorafenib group. The recommended tivozanib dose is 1.34 mg given once daily as an oral tablet for 21 consecutive days, followed by 7 days off, every 28 days until patients experience disease progression or intolerable side effects. The most common side effects associated with the use of tivozanib included conditions such ashypertension, fatigue and diarrhea. Available on the market as of March 22, 2021, Fotivda® offers a new treatment option for a growing number of patients with relapsed or refractory RCC in the U.S.

FDA Approvals

Recent FDA Approvals

Novel Drug Approval: Fotivda® (tivozanib)
Oral capsule indicated to treat adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior therapies [3/10/21 – AVEO PHARMACEUTICALS INC]

Novel Drug Approval: Azstarys™ (serdexmethylphenidate and dexmethylphenidate)
Oral capsule approved for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older [3/2/21 – COMMCAVE THERAPEUTICS SA]

New Generics

New Generic Medications Entering the Marketplace

Azopt® (brinzolamide)
Indication: Treatment of elevated pressure inside the eye in patients with ocular hypertension or open-angle glaucoma.
Dosage Form/Strength: 1% ophthalmic suspension (10 and 15 mL)
Average Wholesale Price (AWP): Generic = $37 | Brand = $41

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