PULSE

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Clinical Update

FDA Approves Farxiga® for use in Certain Heart Failure Patients

On May 5, 2020, the U.S. Food and Drug Administration (FDA) published a press release announcing the approval of Farxiga® (dapagliflozin) oral tablets to reduce the risk of cardiovascular death and hospitalization due to a type of heart failure known as reduced ejection fraction (HFrEF) in adult patients with or without diabetes. Farxiga® is a well-established treatment for type-2 diabetes, but the approval of this additional indication has made it the first and only medication in its class to treat patients with heart failure. The approval was granted under the FDA's Priority Review designation, which is granted for drugs that would significantly improve the safety or effectiveness of treating a serious condition if approved. Clinical trials evaluating the medication showed that Farxiga® significantly improved survival and reduced the need for hospitalizations in adult patients diagnosed with HFrEF compared to placebo. According to the CDC, heart failure is estimated to contribute to one in eight deaths and affect over 6 million Americans.

Safety First

MasterPharm, LLC. Recalls Finasteride Plus Capsules Found to Contain Undeclared Blood Pressure Drug

On May 11, 2020, the FDA published a company announcement on behalf of MasterPharm, LLC., informing consumers of a voluntary nationwide recall of one lot of 1.25mg capsules of Finasteride Plus. Finasteride prescribed at this dosage is generally used to treat hair loss. The recall was initiated due to the presence of undeclared minoxidil, a medication used to treat high blood pressure, at levels higher than in FDA approved products. Ingestion of undeclared minoxidil could result in low blood pressure, a rapid heartbeat, and swelling, and could subsequently increase the risk of developing heart failure or other heart damage. The manufacturer has received 33 reports of adverse events and has arranged for the return and replacement of all recalled products. Consumers are advised to contact their health care providers if they are experiencing issues that could be related to taking this product.

From the Industry

Triple Therapy Combination Shows Promising Results in Treatment of H. Pylori Infections

On May 5, 2020, results of a clinical trial were published in the Annals of Internal Medicine which evaluated the use of an alternative three drug combination therapy, referred to as RHB-105, for H. Pylori infection. The trial assessed the eradication rate of H. Pylori infection, a bacterial infection commonly affecting the digestive tract, using RHB-105 compared to a two-ingredient therapy containing amoxicillin and omeprazole only. Results of the trial showed that patients treated with RHB-105 had a significantly higher eradication rate. In addition, the trial also showed that eradication rates were not affected by bacterial resistance to metronidazole or clarithromycin, two other antibiotics that can be used to treat H. Pylori infections. The results suggest that RHB-105 may have potential as an effective first-line treatment of H. Pylori infections.

FDA Approvals

Recent FDA Approvals

Novel Drug Approval: Tabrecta™ (capmatinib)
Oral tablet for the treatment of adult patients with a specific type of metastatic lung cancer [5/6/2020 – Accelerated Approval; Breakthrough Therapy; Orphan Drug; Priority Review – NOVARTIS PHARMS CORP]

Novel Drug Approval: Retevmo™ (selpercatinib)
Oral capsule for the treatment of adult patients with a type of lung cancer and adult and pediatric patients 12 years and older with certain forms of thyroid cancer [5/8/2020 – Accelerated Approval; Breakthrough Therapy; Orphan Drug; Priority Review – LOXO ONCOLOGY INC]

Novel Drug Approval: Qinlock™ (ripretinib)
Oral tablet for the treatment of adult patients with gastrointestinal stromal tumors (GIST) [5/15/2020 – Breakthrough Therapy; Fast Track; Orphan Drug; Priority Review – DECIPHERA PHARMACEUTICALS LLC]

New Generics

New Generics Entering the Marketplace

Aptensio XR™ (methylphenidate hydrochloride extended-release capsules)
Indication: Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older
Dosage Form/Strength: 10MG, 15MG, 20MG, 30MG, 40MG, 50MG, 60MG Oral Capsule
Average Wholesale Price (AWP): Generic = $255 | Brand = $301

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