PULSE

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Pharmacy Benefit Dimensions®

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Clinical Update

FDA Approves First Treatment for Children with Rare Genetic Disorder

On April 10, 2020, the U.S. Food and Drug Administration (FDA) approved Koselugo™ (selumetinib) oral capsules, the first approved treatment for children ages 2 and older diagnosed with a rare genetic disorder known as neurofibromatosis type 1 (NF1). Koselugo™ is approved to treat tumors (plexiform neurofibromas) caused by NF1, which typically involve the nerves and cause disfiguring and debilitating effects. Koselugo™ blocks a specific enzyme which has been shown to help stop the growth of tumor cells. Clinical trials evaluating the medication indicated that while no patients taking Koselugo™ had complete disappearance of their tumors, the majority of patients (66%) did experience a significant (>20%) reduction in the size of their tumors confirmed by imaging (MRI). NF1 is typically diagnosed in early childhood and is estimated to appear in about 1 of every 3,000 infants.

Safety First

FDA Requests Withdrawal of all Ranitidine Products from the Market

On April 1, 2020, the FDA requested the immediate removal of all prescription and over-the-counter (OTC) ranitidine (branded Zantac®) products from the market. This is the latest update from the ongoing investigation of the contamination of ranitidine products with N-nitrosodimethylamine (NDMA), which is classified as a probable cancer-causing substance by the International Agency for Research on Cancer (IARC). The FDA has determined the level of impurity in some ranitidine products increases over time, especially if stored above room temperature, which may lead to consumer exposure of unacceptable levels of NDMA. The FDA has advised consumers to stop taking ranitidine products, dispose of them properly, and talk to their health care professionals about alternative treatments to use for their condition.

From the Industry

Oral Diabetes Medicine Shows Overwhelming Benefit in Chronic Kidney Disease

On March 30, 2020, AstraZeneca announced that an ongoing clinical trial evaluating effects of Farxiga® (dapagliflozin) on kidney- and heart-related adverse outcomes in patients with chronic kidney disease will be stopped early due to signs of significant efficacy. Farxiga® belongs to a class of medications known as sodium-glucose co-transporter 2 (SGLT2) inhibitors, which are non-insulin medicines traditionally used in combination with diet and exercise to help treat diabetes. Early results of the study indicated that patients with or without diabetes taking Farxiga® experienced significant renal and cardiovascular benefit over those taking placebo. As a result, an independent Data Monitoring Committee (DMC) recommended to stop the trial early. AstraZeneca has announced that the full results of the study will be submitted for medical presentations and that they will begin to discuss regulatory filings with global health authorities.

FDA Approvals

Recent FDA Approvals

Novel Drug Approval: Koselugo™ (selumetinib)
Oral capsule for the treatment of neurofibromatosis type 1 (NF1) in pediatric patients aged two years and older [4/10/2020 – Orphan Drug; Priority Review; Rare Pediatric Disease – ASTRAZENECA LP]

New Combination: dolutegravir/lamivudine/tenofovir disoproxil fumarate
Oral tablet for the treatment of HIV infection in adult and pediatric patients weighing at least 40kg [4/13/2020 – CELLTRION INC]

New Formulation: Jelmyto™ (mitomycin)
Renal solution for the treatment of a type of cancer of the urinary tract known as Low-grade Upper Tract Urothelial Cancer (LG-UTUC) [4/15/2020 – Breakthrough Therapy; Orphan Drug; Priority Review – UROGEN PHARMA LTD]

New Generics

New Generics Entering the Marketplace

Proglycem® (diazoxide)
Indication: Hypoglycemia
Dosage Form/Strength: 50 MG/ML Oral Suspension
Average Wholesale Price (AWP): Generic = **$372** | Brand = **$413**

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