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Clinical Update

FDA Approves Medication for Treatment of Infants and Children with HIV

On June 12, 2020, The U.S. Food and Drug Administration (FDA) approved Tivicay® (dolutegravir) oral tablets and Tivicay® PD oral tablets for suspension to treat HIV-1 infections in pediatric patients at least four weeks of age with a weight of at least 3 kilograms (6 pounds, 10 ounces) in combination with other HIV drugs used in standard treatment. The approval was granted under the FDA's Priority Review designation, which directs attention to the review of drugs that may result in a substantial improvement in treatment of a serious condition when compared to currently available therapies. Prior to this approval, Tivicay® was approved for use in children 12 years and older with a weight of at least 40 kilograms (88 pounds, 3 ounces) Clinical trials evaluating the medication showed that a majority of pediatric patients treated with Tivicay® or Tivicay® PD showed measurable improvement in levels of detectable virus in the blood at 24 and 48 weeks of treatment (62% and 69%, respectively). In addition, the study showed that patients on the medications had higher levels of CD4 cells, which help the body fight against infections. This approval has helped expand treatment options for the youngest age-group of HIV patients, offering a once-daily treatment option that may contribute to improving quality of life and extending lifespan.

Safety First

FDA Alerts the Public About Potential Malfunction of Epinephrine Auto-Injector Devices

On June 1, 2020, the FDA alerted the public of a possible safety risk associated with epinephrine 0.3mg auto-injector devices manufactured by Impax Laboratories LLC, a subsidiary of Amneal Pharmaceuticals LLC. The notification was initiated due to certain lots of these devices missing the yellow "stop collar" component, which could cause the device to deliver a double dose of the drug if used. Epinephrine is commonly used to provide relief of potentially life-threatening symptoms during an allergic reaction, also known as anaphylaxis. The FDA has provided directions for patients and health care professionals on proper inspection of the devices and recommends inspection as soon as possible. If the yellow stop collar is not present, the FDA advises providers not to dispense the device and patients not to use the device. However, if the stop collar is present, patients should consider the device safe to use. Amneal has offered replacement of affected devices at no cost.

From the Industry

Orphan Drug Designation Granted to Pravibismane for Lung Infections in Patients with Cystic Fibrosis

On May 27, 2020, Microbion Pharma Corp issued a press release announcing the FDA's designation of their inhalation of pravibismane as an Orphan Drug. Orphan Drug designation is given to medications that intend to offer a treatment option for a rare disease or condition that affects fewer than 200,000 people in the U.S. Pravibismane is indicated for the treatment of lung infections in cystic fibrosis (CF) patients, a chronic health issue for many afflicted with CF, and it is the first drug in a new class of anti-infectives. It has demonstrated effectiveness against a wide range of bacteria, including drug-resistant bacteria, that are commonly recognized as serious threats to patients with CF. Pravibismane was also granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA.

FDA Approvals

Recent FDA Approvals

Novel Drug Approval: Uplizna™ (inebilizumab-cdon)
Intravenous injection for the treatment of patients with an autoimmune disease known as neuromyelitis optica spectrum disorder which can cause a variety of symptoms including pain in the eyes and weakness/numbness in the arms and legs [6/11/2020 – Orphan Drug – VIELA BIO]

New Dosage Form: Tivicay® PD (dolutegravir sodium)
Oral tablet for suspension used for the treatment of HIV-1 infection in pediatric patients at least 4 weeks of age with a weight of at least 3 kg (6 lbs, 10oz) [6/12/2020 – Priority Review – VIIV HLTHCARE]

Novel Drug Approval: Zepzelca™ (lurbinectedin)
Intravenous injection for the treatment of adult patients with metastatic small cell lung cancer (SCLC) that progresses on or after chemotherapy [6/15/2020 – Orphan Drug; Priority Review – PHARMA MAR USA INC]

Preventative Services Update

Affordable Care Act (ACA) Preventative Services Update

Updates to United States Preventative Services Task Force Recommendations
The USPSTF is an independent review panel that works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications. USPSTF bases its recommendations on the evidence of both the benefits and harms of the service. USPSTF Grade A and B recommendations must take effect no later than the first day of the plan year on or after one year following the recommendation effective date for Affordable Care Act (ACA) compliant plans.

Below are updates to medications affected by USPSTF Grade A and B recommendations that take effect starting 7/1/2020 upon plan renewal for ACA compliant plans:

Addition: Descovy® 200mg-25mg, Truvada® 200mg-300mg
Removal: Iron supplements

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