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Pharmacy Benefit Dimensions®

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Clinical Update

First Treatment for Ebola Virus Approved by the FDA

On October 14, 2020, the U.S. Food and Drug Administration (FDA) announced the approval of Inmazeb™ (atoltivimab, maftivimab, and odesivimab-ebgn), the first ever treatment for Zaire ebolavirus, one of the four viral strains of Ebola virus. Ebola virus has been shown to cause a fatal disease in infected humans. Inmazeb™ prevents Ebola virus cells from entering human host cells by attaching and blocking glycoproteins found on the surface of the virus and infected host cells that would normally facilitate fusion and allow entry. The efficacy of Inmazeb™ was studied in the PALM trial, which enrolled patients with confirmed cases of Ebola virus disease (EVD). Of the patients enrolled in the trial, 154 received a single intravenous infusion of Inmazeb™, while another group of 168 patients received an investigational control therapy. The primary measure of efficacy was mortality at the 28-day mark. Results showed a 17.2 % lower death rate at 28 days in individuals who were treated with Inmazeb™ compared to those in the control group (33.8% vs 51%). Inmazeb™ received an Orphan Drug designation, and provides a novel treatment option for patients infected with Ebola virus, a significant step forward in the treatment of infectious disease.

Safety First

FDA Recommends Limited Use of NSAIDs in Pregnancy

On October 15, 2020, the FDA released a Drug Safety Communication regarding new requirements for prescribing information and Drug Facts Labels for nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and naproxen, to ensure their safe use in pregnancy. NSAIDs available alone or in combination with other products, are widely used for treating pain and fever as well as other medical conditions such as arthritis, headaches, colds and the flu. Over-the-counter (OTC) NSAIDs currently have associated warnings against the use within the last 3 months of pregnancy as they have been shown to cause problems in the unborn child as well as complications during delivery. The FDA recommends that NSAID use, when deemed appropriate by a healthcare professional, be limited between weeks 20 to 30 of pregnancy and should be avoided altogether after week 30. Use of NSAIDs in weeks 20 or later in pregnancy have been found to potentially cause rare but serious kidney problems in an unborn baby. If NSAID treatment is necessary during weeks 20 to 30 of pregnancy, use should be limited to the lowest effective dose for the shortest duration possible. If treatment exceeds 48 hours, ultrasound monitoring of amniotic fluid should be considered. These new recommendations do not apply to low dose 81mg aspirin, which may be prescribed for certain medical conditions in pregnancy. To ensure safety for both the mother and child, pregnant and breastfeeding women should contact a health care professional when considering using NSAIDs.

From the Industry

FDA Approves Kalydeco® for the Treatment of CF in Infants as Young as 4 Months Old

On September 25, 2020, Vertex Pharmaceuticals Inc. announced the FDA approval of Kalydeco® for use in patients with Cystic Fibrosis (CF) 4 months or older with one of several various gene mutations that has been shown to be responsive to treatment with Kalydeco®. CF is a progressive, genetic disease that causes persistent lung infections, limits a person's ability to breathe over time, and can often decrease life expectancy. Individuals with CF have a modification in their CF transmembrane conductance regulator (CFTR) gene that causes the CFTR protein, to be absent or dysfunctional. This defect, which can be identified via genetic testing, reduces movement of chloride ions out of the cell, which normally attracts water to hydrate the cell surface and eliminate excess mucus in the lungs. This results in a buildup of dehydrated, thick mucus which ultimately causes obstruction, infection and inflammation. Kalydeco® is a CFTR modulator that improves the activity of this dysfunctional protein. This approval, which expands access to treatment to CF patients between 4 and 6 months old, is based on data from a 24-week Phase 3 open-label safety cohort (ARRIVAL) which consisted of 6 children between 4 and less than 6 months old who had one of 10 mutations that Kalydeco® has previously shown a therapeutic benefit for. Enrolled patients were evaluated for safety as assessed by adverse events and clinical laboratory measurements. Trial results confirmed the cohort observed to have a similar safety profile that was seen in older CF patients. The benefit of starting treatment as early as possible may be a potential modification in the course of disease.

FDA Approvals

Recent FDA Approvals

New Biologic: Inmazeb™ (atoltivimab, maftivimab, and odesivimab-ebgn)
Intravenous injection approved for the treatment of Ebola virus disease (EVD) caused by Zaire ebolavirus in newborns who are born to an infected mother, as well as adult and pediatric patients [10/14/20 – Orphan Drug – REGENERON PHARMACEUTICALS]

New Generics

New Generics Entering the Marketplace

Tykerb® (lapatinib)
Indication: HER2 + Advanced or Metastatic Breast Cancer
Dosage Form/Strength: 250MG Oral Tablet
Average Wholesale Price (AWP): Generic = $9,021 | Brand = $10,024

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