PULSE

Your source for the latest industry trends and drug information news.

Pharmacy Benefit Dimensions®

Volume 2 | Issue 18
September 15, 2020
pbdrx.com

Clinical Update

FDA Approves Treatment for Neuromyelitis Optica Spectrum Disorder

On August 17, 2020, the U.S. Food and Drug Administration (FDA) approved Enspryng™ (satralizumab-mwge) subcutaneous injection to treat neuromyelitis optica spectrum disorder (NMOSD) in adult patients with anti-aquaporin 4 (AQP4) antibodies. The majority of all patients diagnosed with NMOSD have anti-AQP4 antibodies, which are believed to activate immune responses in the body. NMOSD, also known as Devic disease, is a rare, chronic disorder of the brain and spinal cord that is characterized by inflammation of the optic nerves and spinal cord which can result in loss of vision, pain and even paralysis below a certain level on the body. Enspryng™ works by binding to IL-6 receptors and inhibiting the signaling of IL-6, a vital component of the inflammatory response driving the disease. The safety and efficacy of the medication were evaluated in two clinical trials that spanned 96 weeks - one with 95 adult patients with NMOSD and one with 76 adult patients with NMOSD. In both trials, some patients were positive for anti-AQP4 antibody while others were negative. Results showed no benefit in patients that were anti-AQP4 antibody negative in either trial. However, a majority (64/95 and 52/76) of the patients were anti-AQP4 antibody positive and saw a 74 and 78 percent reduction in NMOSD relapses, respectively. Enspryng™ was awarded Fast Track and Orphan Drug designations. Enspryng™ is the third drug developed this year to treat NMOSD, which affects an estimated 4,000-8,000 Americans.

Safety First

FDA Removes Boxed Warning on Canagliflozin

On August 26, 2020, the FDA announced the removal of the Boxed Warning for risk of leg and foot amputations for diabetes medications containing the active ingredient canagliflozin, such as brand name Invokana®, Invokamet® (canagliflozin and metformin) and Invokamet®XR (canagliflozin and metformin ER). Canagliflozin is commonly used as an antidiabetic therapy in addition to diet and exercise for the management of Type 2 diabetes mellitus and works by inhibiting reabsorption of excess sugar by the kidneys, thereby decreasing sugar levels circulating through the body. The removal of the Boxed Warning was based on review of data from several new clinical trials, which also extended the use of canagliflozin to include risk reduction of heart-related events and worsening of kidney functions in patients with Type 2 diabetes mellitus. With appropriate monitoring for adverse effects, the risk of amputation is lower than what was previously described. Although the Boxed Warning has been removed, the amputation risk remains in the Warnings and Precautions section of the prescribing information. Furthermore, the FDA has emphasized the importance of preventative footcare and regular monitoring of pain, tenderness, ulcers and infections in the legs and feet by both health care professionals and patients.

From the Industry

FDA Denies Application for Treatment of Rheumatoid Arthritis with Filgotinib

On August 18, 2020, Gilead Sciences received a Complete Response Letter(CRL) from the FDA regarding Gilead Sciences' New Drug Application (NDA) for filgotinib, an investigational treatment for moderate to severe rheumatoid arthritis (RA). Filgotinib belongs to a medication class known as Janus Kinase 1 (JAK1) inhibitors, which block a key enzyme in the inflammatory response that contributes to development of RA. Filgotinib is intended to be a convenient oral treatment option for patients who have not experienced symptom relief with conventional disease-modifying anti-rheumatic drugs (DMARDs), such as methotrexate. The CRL explained the FDA's decision not to approve the application in its present form due to concerns regarding filgotinib's observed effects on reduction in sperm parameters, and the overall safety and efficacy profile of the 200 mg trial dose. The FDA requested data from two ongoing studies (MANTA and MANTA-RAy) to gather more information. Results are expected in the first half of 2021.

FDA Approvals

Recent FDA Approvals

New Formulation or New Manufacturer: Cystadrops® (cysteamine hydrochloride)
Ophthalmic solution for the treatment of corneal cystine crystal deposits in adults and children with cystinosis [8/19/2020 – RECORDATI RARE]

New Active Ingredient: Pemetrexed
Intravenous injection for the treatment of non-squamous non-small cell lung cancer (NSCLC) that has not responded to other chemotherapy, or returns following completion of previous therapy [8/21/2020 – ACTAVIS LLC]

Novel Drug Approval: Winlevi® (clascoterone)
Topical cream for the treatment of acne vulgaris in patients ages 12 and older [8/26/2020 – CASSIOPEA SPA]

New Dosage Form: Xaracoll® (bupivacaine HCl)
Implant to provide pain relief for up to 24 hours following open inguinal hernia repair surgery [8/28/2020 – INNOCOLL PHARMACEUTICALS]

New Generics

New Generics Entering the Marketplace

Symfi®/Symfi Lo® (efavirenz/lamivudine/tenofovir disoproxil fumarate)
Indication: HIV-1 Infection
Dosage Form/Strength: 600/300/300 MG and 400/300/300 MG Tablets
Average Wholesale Price (AWP): Generic = $1,725.90 | Brand = $1,961.33

Chief Author: Dana Ranallo, PharmD
Contributing Author: James Pufpaff, PharmD/MBA Candidate