PULSE

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Pharmacy Benefit Dimensions®

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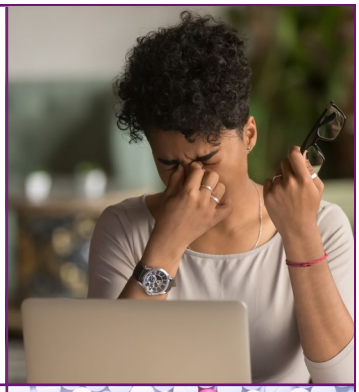
Clinical Updates



FDA approves breakthrough therapy for thyroid eye disease

On Jan. 21, 2020, the U.S. Food and Drug Administration (FDA) approved Tepezza™ (teprotumumab-trbw) intravenous injection as the first treatment for thyroid eye disease. Thyroid eye disease is an autoimmune disorder caused by an overactive thyroid that results in bulging of the eyes. This bulging produces symptoms such as irritation, swelling, and double vision which can lead to difficulty in completing daily tasks such as driving and reading. In 2 separate clinical trials, 71% and 83% of respective patients that were administered Tepezza™ experienced a greater than two-millimeter reduction in eye bulging. As the first approved treatment for the condition, Tepezza™ provides a new alternative to invasive surgeries previously used. Thyroid eye disease is estimated to affect about 16 of every 100,000 females and 3 of every 100,000 males.

Safety First

FDA strengthens warning for clozapine's impact on bowel activity

On Jan. 28, 2020, the FDA issued a Drug Safety Communication directed to patients and health professionals strengthening the existing bowel-related warnings on the common schizophrenia medication known as clozapine (Clozaril®, Fazaclo® ODT, Versacloz®). The FDA has emphasized the risk of progression from constipation to more serious bowel problems, such as complete blockage of the bowel. Although uncommon, this serious complication can lead to hospitalization or even death if not treated promptly. The FDA has advised patients taking clozapine to seek medical attention if they notice symptoms of bowel problems and has advised health care professionals to screen patients for increased risk, monitor progress, and adjust therapy appropriately.

From the Industry

FDA grants Dupixent® priority review for treatment of skin condition in children

On Jan. 28, 2020, Regeneron Pharmaceuticals, Inc. announced that the FDA granted Priority Review for its application to expand the use of their biologic medication, Dupixent® (dupilumab). Dupixent® is currently approved to treat moderate-to-severe atopic dermatitis that is not adequately controlled by other prescription therapies in patients age 12 years and older. Atopic dermatitis, also known as eczema, is a type of inflammation of the skin that results in itchy, cracked, red, and swollen skin. The application under review with the FDA, is for an expanded use of Dupixent® for children 6 to 11 years old. Priority Review designation ensures the agency will decide on the application within 6 months – significantly faster than the standard review period of 10 months. If approved, Dupixent® would be the first biologic medication available in the U.S. to treat this patient population.

Recent FDA Approvals

Novel Drug Approval: Tepezza™ (teprotumumab-trbw)
Intravenous injection for the treatment of thyroid eye disease [1/21/2020 – Breakthrough Therapy; Fast Track; Orphan Drug; Priority Review – HORIZON THERAPEUTICS IRELAND]

Novel Drug Approval: Tazverik™ (tazemetostat)
Oral tablet for the treatment of patients age 16 years and older with a rare type of soft tissue cancer, known as epithelioid sarcoma, that is not surgically removable [1/23/2020 – Accelerated Approval; Orphan Drug; Priority Review – EPIZYME INC]

New Formulation: Bynfezia Pen™ (octreotide acetate)
Subcutaneous injection for the reduction of growth hormone levels and treatment of diarrhea associated with cancerous tumors in adult patients [1/28/2020 – SUN PHARM INDS LTD]

New Generics Entering the Marketplace

K-Tab® (Potassium Chloride Extended-Release tablets, USP)
Indication: Potassium supplementation
Dosage Form/Strength: 20 mEq tablet
Average Wholesale Price (AWP): Generic = $19 | Brand = $30

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