PULSE

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Pharmacy Benefit Dimensions®

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Clinical Updates

New treatment for adults with migraine approved by FDA

On Dec. 23, 2019, the U.S. Food and Drug Administration (FDA) approved Ubrelvy™ (ubrogepant) oral tablets for the acute treatment of migraine in adult patients. Ubrelvy™ belongs to a class of medications known as calcitonin gene-related peptide (CGRP) antagonists, that work by blocking the molecule that is thought to cause migraine pain. While there are several medications in this class indicated for the prevention of migraine, Ubrelvy™ offers a new option for acute treatment of migraine. Results of the ACHIEVE II clinical trial showed significant improvement in both pain freedom and most bothersome migraine symptom two hours after treatment. According to the Migraine Research Foundation, mirgraine disease affects 39 million people in the U.S. and 1 billion worldwide.

Safety First

FDA warns of dangerous breathing issues associated with common seizure and nerve pain medicines

On Dec. 19, 2019, the FDA issued a Safety Communication targeted at patients using gabapentinoids with respiratory risk factors, reporting concerns that the class of drugs may contribute to serious breathing problems in certain patients. Gabapentinoids are commonly used to treat seizure and nerve pain and includes medications such as gabapentin (Neurontin®, Gralise®, Horizant®) and pregabalin (Lyrica®, Lyrica CR®). The Safety Communication warns that breathing difficulties may occur in patients using gabapentinoids if they are elderly, have concurrent respiratory conditions that reduce lung function, such as COPD, and/or are using concurrent medications that suppress the central nervous system, such as opioids. The FDA is now requiring new warnings about the risk of respiratory distress to be added to the prescribing information of gabapentinoids and advises patients to seek medical attention immediately if they notice symptoms of respiratory problems.

From the Industry

Anifrolumab shows promise in treatment of systemic lupus erythematosus (SLE)

On Dec. 18, 2019, The New England Journal of Medicine released results of a phase III clinical trial that evaluated the use of anifrolumab in the treatment of systemic lupus erythematosus (SLE), an autoimmune disease that causes inflammation and tissue damage in the affected organs. The efficacy of anifrolumab was evaluated using a combination of clinical measures that considered the level of disease activity and organ system involvement, among other factors. Patients treated with anifrolumab consistently demonstrated a higher response rate and lower disease activity than those treated with placebo. If approved, anifrolumab will provide a new option to patients who have failed to respond to first-line therapy.

Recent FDA Approvals

Novel Drug Approval: Caplyta® (lumateperone)
Oral capsule for the treatment of schizophrenia in adult patients [12/20/2019 – INTRA-CELLULAR THERAPIES INC]

Novel Drug Approval: Enhertu® (fam-trastuzumab deruxtecan nxki)
Intravenous infusion for the treatment of metastatic breast cancer in patients who have previously received two or more specific treatment regimens [12/20/2019 – Accelerated Approval – DAIICHI SANKYO]

Novel Drug Approval: Ubrelvy™ (ubrogepant)
Oral tablet for the acute treatment of migraine with or without aura in adult patients [12/23/2019 – ALLERGAN]

New Generics Entering the Marketplace

Nuvaring® (etonogestrel/ethinyl estradiol)
Indication: Contraception
Dosage Form/Strength: 0.12 MG/0.015MG vaginal ring
Average Wholesale Price (AWP): Generic = $185 | Brand = $195

Travatan Z® (travoprost)
Indication: Glaucoma
Dosage Form/Strength: 0.004% ophthalmic solution
Average Wholesale Price (AWP): Generic = $207 | Brand = $221

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