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Clinical Update

FDA Approves New Medication for Rare Seizure Disorder

On June 25, 2020, The U.S. Food and Drug Administration (FDA) announced the approval of Fintepla® (fenfluramine) oral solution to treat seizures associated with Dravet syndrome in patients age 2 years and older. Also known as Severe Myoclonic Epilepsy of Infancy (SMEI), Dravet syndrome is a serious and rare seizure disorder that often begins within the first year of life of previously healthy children. Clinical trials evaluating the medication showed that patients treated with Fintepla® experienced fewer convulsive seizures, with a noticeable reduction beginning around 3 to 4 weeks, when compared to those treated with placebo. Fintepla® is part of a restricted distribution program that follows a risk evaluation and mitigation strategy (REMS) due to a boxed warning that associates the medication with valvular heart disease and pulmonary arterial hypertension (PAH). The approval was granted under the FDA's Priority Review and Orphan Drug designations.

Safety First

GSK Consumer Healthcare Issues Recall on Children's Cough and Cold Medicines

On June 18, 2020, GlaxoSmithKline (GSK) Consumer Healthcare announced a voluntary nationwide recall of two children's cough and cold products. Two lots of Children's Robitussin® Honey Cough and Chest Congestion DM (dextromethorphan/guaifenesin) and one lot of Children's Dimetapp® Cold and Cough (brompheniramine/dextromethorphan/phenylephrine) were recalled at the retail level due to incorrect dosing cups included in the package. The dosing cups had a 20 mL measurement but were missing smaller 5 mL and 10 mL markings. If caregivers do not notice this discrepancy, there is potential for accidental overdose, which may result in symptoms such as impaired coordination, excessive stimulation/sedation, dizziness, or fainting. So far, GSK Consumer Healthcare has not received any reports of adverse events and has notified distributors and retailers to arrange for return of the recalled products.

From the Industry

FDA Grants Priority Review to Myovant Sciences' Relugolix

On June 22, 2020, Myovant Sciences announced the FDA has granted Priority Review to their new oral formulation of relugolix, a medication used for advanced prostate cancer. In clinical trials, relugolix was found to be more effective than the current standard of care (leuprolide injections). Relugolix was also found to be associated with a much lower risk for major adverse heart-related events compared to leuprolide. If granted approval, relugolix would be the first and only oral medicine in its class (GnRH receptor antagonist) approved for the treatment of advanced prostate cancer. The FDA intends to make a final approval decision by December 20, 2020.

FDA Approvals

Recent FDA Approvals

New Dosage Form: Gimoti™ (metoclopramide)
Intranasal spray for the treatment of acute and recurrent diabetic gastroparesis in adults [6/19/2020 – EVOKE PHARMA INC]

New Dosage Form: Fintepla® (fenfluramine)
Oral solution used for the treatment of seizures associated with Dravet syndrome in patients age 2 and older [6/25/2020 – Orphan Drug; Priority Review – ZOGENIX INC]

Novel Drug Approval: Dojolvi™ (triheptanoin)
Oral liquid used as a source of calories and fatty acids for the treatment of pediatric and adult patients with long-chain fatty acid oxidation disorders (FAOD) [6/30/2020 – Orphan Drug – ULTRAGENYX PHARM INC]

New Generics

New Generics Entering the Marketplace

Avelox® (moxifloxacin hydrochloride)
Indication: Skin infection
Dosage Form/Strength: 400 MG/250 ML solution for injection
Average Wholesale Price (AWP): Generic = $55 | Brand = $61

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