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Clinical Pharmacy Update

FDA Approves New ADHD Medication for Children

On April 2, 2021, the U.S. Food and Drug Administration (FDA) approved Qelbree™ (viloxazine) extended-release capsules for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in pediatric patients 6-17 years old. ADHD is a neurological disorder affecting approximately 6 million American children and adolescents, and is categorized by inattention, hyperactivity and impulsivity. Many ADHD medications on the market today, such as Adderall® and Ritalin®, contain stimulant components, which increase the activity of the brain and nervous system and are categorized as controlled substances as they carry a potential for abuse. Qelbree™ is the first ADHD medication for children to be approved in over a decade and will be categorized with other non-stimulant ADHD medications, such as Intuniv® and Straterra®. Qelbree™ works by increasing levels of norepinephrine (NE), a neurotransmitter that helps transmit signals in the brain. Individuals with ADHD may have decreased production of NE, which can lead to issues with cognitive functioning such as inability to focus and difficulties with organization. Results from a Phase 3 study including 477 pediatric patients 6-17 years old showed that Qelbree™ reduced symptoms of inattention and hyperactivity by about 50% when compared to placebo. Common side effects experienced by those taking Qelbree™ included sleepiness, fatigue, decreased appetite and headache. Positive results were reported in late-stage clinical trials for use of the drug in adults, which is expected to support a request for a label expansion later this year to approve the use in patients age 18 and older. Qelbree™ will provide an additional alternative to stimulant medications for the treatment of ADHD.

Drug Safety

Lamotrigine May Increase Risk of Heart Rhythm Problems in Patients with Heart Disease

On March 31, 2021, the FDA released a Drug Safety Communication announcing the drug lamotrigine may potentially increase the risk of heart rhythm complications in patients with heart disease. Lamotrigine, a drug that has been on the market for over 25 years, is approved for use in seizure disorders as well as bipolar I disorder. Through studies, lamotrigine has been shown to influence the movement of sodium – a common electrolyte found in the body – in and out of cells. Electrolytes such as sodium, potassium and calcium help trigger and conduct electrical impulses in the heart, and imbalances in these electrolytes may lead to abnormal heart rhythms. The FDA initiated an investigation into the drug's effects after receiving reports of abnormal findings in patients receiving an electrocardiogram (ECG), a medical test designed to evaluate heart rhythm, among other serious problems such as chest pain, loss of consciousness and cardiac arrest. The results of the investigation, which was performed in a laboratory setting rather than in humans or animals, has prompted an update to lamotrigine's prescribing information. Health care professionals are advised to evaluate whether the benefits of lamotrigine outweigh the potential risks for arrythmia in patients, particularly those with heart disorders. Individuals who are currently taking lamotrigine are advised to not change the way they are taking their medication without first talking to their prescriber as abrupt discontinuation could cause uncontrolled seizures, or new or worsening mental health problems. The FDA is currently conducting additional studies on other medications within the same class and will release new information once results become available. Anyone who experiences an adverse reaction to lamotrigine, or any other medication, is advised to report it to the FDA's MedWatch Adverse Event Reporting Program.

From the Pharmaceutical Industry

Pause on Johnson & Johnson Vaccine Lifted by FDA and CDC

On April 23, 2021, the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) lifted the recommended pause on the Johnson & Johnson (J&J) COVID-19 vaccine administration. Ten days prior, both organizations issued a statement calling for a pause of the single-dose vaccine in the U.S. after a rare blood clotting disorder was reported in six American women between the ages of 18 and 48. This updated recommendation has come following two meetings of the CDC Advisory Committee on Immunization Practices and data review from both the CDC and FDA.. Out of 8 million doses administered, 15 cases of the blood disorder have now been identified in patients receiving the J&J vaccine, all of which were reviewed by the committee. Through extensive analysis, the organizations have concluded that the benefits of the vaccine outweigh potential risks in adults ages 18 and older and administration of the vaccine should resume and the risk of developing the disorder in the general population is extremely low. The J&J vaccine product label and associated vaccine fact sheet provided to patients have been updated to include warning of the risk of a rare blood clotting disorder. In addition to this investigation, both the FDA and CDC have performed widespread outreach to providers to ensure they are prepared to recognize and help manage these rare events and widespread safety monitoring will continue. Health care providers have been asked to report any adverse events related to the COVID vaccine to the Vaccine Adverse Event Reporting System.

FDA Approvals

New FDA Drug Approvals

Novel Drug Approval: Qelbree™ (viloxazine hydrochloride)
Oral capsule approved for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6-17 years old [4/2/21 – SUPERNUS PHARMS]

Novel Drug Approval: Nextstellis™ (drospirenone and estetrol)
Oral tablet approved for use by females of reproductive potential to prevent pregnancy [4/15/21 – MAYNE PHARMA]

New Generics

New Generic Medications Entering the Marketplace

Hysingla ER® (hydrocodone bitartrate extended-release)
Indication: Pain management
Dosage Form/Strength: 20MG, 30 MG, 40 MG, 60 MG, 80 MG, 100 MG, and 120 MG tablet
Average Wholesale Price (AWP): Generic = 20MG – 120MG ($11.01-$52.75) | Brand = 20MG – 120 MG ($12.59-$64.69)

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