PULSE

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Clinical Update

FDA Approves New Add-On Therapy for Parkinson's Disease

On April 27, 2020, Neurocrine Biosciences published a press release announcing the U.S. Food and Drug Administration's (FDA) approval of Ongentys® (opicapone) oral capsules as an add-on treatment to carbidopa-levodopa for Parkinson's Disease (PD). More specifically, Ongentys® is indicated for use in PD patients experiencing "off episodes," which are periods of time between treatments when medicine wears off and symptoms, such as tremor and movement difficulty, recur. Ongentys® aims to improve symptoms by blocking an enzyme that breaks down levodopa, the mainstay treatment for symptom control in PD. Clinical trials evaluating the medication showed that Ongentys® significantly reduced "off time" and improved bothersome symptoms when compared to placebo. It is estimated that 500,000 Americans are currently diagnosed with PD.

Safety First

Avet Pharmaceuticals Inc. Recalls Several Lots of Tetracycline Capsules from the Market

On April 16, 2020, the FDA published a company announcement on behalf of Avet Pharmaceuticals Labs Inc., informing consumers of a voluntary nationwide recall of certain lots of 250mg and 500mg capsules of tetracycline. Tetracycline is an antibiotic used to treat various types of bacterial infections and can also be prescribed to treat severe acne. The recall was initiated as result of unacceptable test results revealing low drug dissolution levels, which may indicate issues with the medicine's ability to dissolve in the body. Incomplete dissolution could result in lower amounts of the medication available to the body to fight infection. This may lead to treatment failures and safety concerns for higher risk individuals, such as the elderly or immunocompromised. To date, there have not been any reports of adverse events, but consumers are advised to contact their health care providers prior to stopping the medication.

From the Industry

New Alzheimer's Disease Medication Meets Primary Endpoint in Phase 2/3 Trial

On April 27, 2020, Axsome Therapeutics announced that AXS-05, a novel, investigational medicine intended for use in Alzheimer's Disease, met the primary endpoint in its clinical trial. Alzheimer's Disease is a type of neurological disorder which can result in a decline in memory and cognitive ability and is often associated with agitation. Axsome aims for AXS-05 to become an FDA-approved treatment for Alzheimer's Disease agitation, for which there are currently no approved therapies. In clinical trials, AXS-05 was found to reduce the frequency of agitation-related behavior, such as restlessness and aggression, in patients with dementia, when compared to placebo. AXS-05 was well tolerated in the trial with drowsiness, dizziness, and diarrhea as the most commonly reported adverse events.

FDA Approvals

Recent FDA Approvals

Novel Drug Approval: Pemazyre™ (pemigatinib)
Oral tablet for the treatment of adult patients with a particular type of cholangiocarcinoma, a rare cancer that targets the bile ducts [4/17/2020 – Orphan Drug; Priority Review – INCYTE CORP]

Novel Drug Approval: Tukysa™ (tucatinib)
Oral tablet for the treatment of adult patients with a certain type of breast cancer, in combination with other therapies [4/17/2020 – Orphan Drug; Priority Review – SEATTLE GENETICS]

Novel Drug Approval: Ongentys® (opicapone)
Oral capsule for the treatment of adult patients with Parkinson's Disease experiencing "off episodes" [4/24/2020 – NEUROCRINE]

New Generics

New Generics Entering the Marketplace

Videx® EC (didanosine)
Indication: HIV
Dosage Form/Strength: 125MG, 200MG, 250MG, 400MG Oral Capsule
Average Wholesale Price (AWP): Generic = $236 | Brand = $330

Soolantra® (ivermectin)
Indication: Rosacea
Dosage Form/Strength: 1% Cream
Average Wholesale Price (AWP): Generic = $648 | Brand = $689

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