

### THE FDA FILE



#### **Gocovri Approved for Treatment of Dyskinesia in Parkinson's Disease**

The FDA has approved Gocovri (amantadine, Adamas Pharmaceuticals) extended release capsules (previously ADS-5102) for treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. The first medicine approved for this indication, Gocovri is a high-dose 274mg amantadine (equivalent to 340mg amantadine HCl) taken once-daily at bedtime that delivers consistently high levels of amantadine during the morning and throughout the day. Gocovri's positive benefit/safety profile was established in two Phase 3 controlled clinical trials in patients with Parkinson's disease with dyskinesia.

The approval is a milestone for Adamas and for the Parkinson's disease community, said Gregory T. Went, PhD, Founder, Chairman, and Chief Executive Officer of Adamas Pharmaceuticals, in a statement. "Gocovri has the potential to help people with Parkinson's disease suffering from dyskinesia by finally providing physicians with an effective tool to address this long-standing unmet medical need."

Although Gocovri is expected to be available in the fourth quarter of 2017, the company is planning a formal launch in January 2018.

#### **Noninvasive Neuromodulation Device for Chronic Intractable Pain Cleared**

The FDA has cleared the Stimpod NMS460 (Xavant Technology), a noninvasive neuromodulation device for the symptomatic relief and management of chronic intractable pain. When applied to the affected area transcutaneously, the device's proprietary hybrid pulsed radiofrequency waveform creates electromagnetic effects similar

to invasive pulsed radiofrequency treatments. It also incorporates nerve-locating technology, featuring a nerve-mapping probe that enables practitioners to locate nerves and evaluate the treatment progress of damaged nerves.

According to the company, case studies have shown instant and dramatic relief of chronic intractable pain with use of the Stimpod NMS460. Beyond chronic intractable pain, the device was also cleared as an adjunct in the management of postsurgical pain, acute pain problems, and pain control due to rehabilitation.



#### **Austedo Approved for Treatment of Tardive Dyskinesia**

The FDA has approved Austedo (deutetrabenazine, Teva Pharmaceutical Industries) tablets for the treatment of tardive dyskinesia in adults. The approval was based on results from two Phase 3 randomized placebo-controlled studies assessing the efficacy and safety of Austedo in reducing the severity of abnormal involuntary movements associated with tardive dyskinesia (AIM-TD and ARM-TD).

Austedo is the second drug approved for the treatment of tardive dyskinesia this year, joining Ingrezza (valbenazine, Neurocrine) as the only two therapies indicated for the condition. Austedo was previously approved for the treatment of chorea associated with Huntington's disease in April 2017.

## **CDC: Epilepsy Rates Rising in US**

New data from the Centers for Disease Control & Prevention suggest that the number of individuals with epilepsy in the United States is on the rise (*Morbidity and Mortality Weekly Report*; 66(31):821-825). Researchers found that epilepsy rates in adults increased from 2.3 million cases to 3 million from 2014 to 2015. In children, there was a slight increase from 2007 to 2015 (450,000 to 470,000). Taken

together, the number of individuals with active epilepsy has reached 3.4 million as of 2015, making up roughly 1.2 percent of the US population. "Public health practitioners, health care providers, policy makers, epilepsy researchers, and other epilepsy stakeholders, including family members and people with epilepsy, can use these findings to ensure that evidence-based programs meet the complex needs of adults and children with epilepsy and reduce the disparities resulting from it," the authors write.

## Gut Bacteria May Play Preventive Role in MS

New findings support the increasingly prominent hypothesis that gut bacteria play a role in autoimmune diseases such as multiple sclerosis. Specifically, a study published in *Cell Reports* (6:1269-1277) shows that bacteria present in the gut known as *Prevotella histicola* may possibly prevent MS. In the study, investigators found that *Prevotella histicola* can suppress experimental autoimmune encephalomyelitis in a human leukocyte antigen class II transgenic mouse model.

The authors further noted that *Prevotella histicola* increases in the frequencies of CD4<sup>+</sup>FoxP3<sup>+</sup> regulatory T cells, tolerogenic dendritic cells, and suppressive macrophages. "Our study provides evidence that the administration of gut commensals may regulate a systemic immune response and may, therefore, have a possible role in treatment strategies for MS," the authors write.

## ALS Treatment Radicava Now Available

Radicava (edaravone, Mitsubishi Tanabe Pharma America), an intravenous therapy indicated for all adult patients diagnosed with amyotrophic lateral sclerosis (ALS), is now available for use in the US. The first FDA-approved ALS treatment option in more than 20 years, Radicava has been shown to slow decline in the loss of physical function in patients with ALS by 33 percent. It is administered in 28-day cycles through an IV. Patients can undergo treatment at an ALS center, physician's office, free-standing infusion center, hospital outpatient department, or through a home infusion provider, depending on their health plan and physician's determination.

Physicians can initiate patient access to the product and the benefits investigation process through the Searchlight Support hub, which provides assistance for people who are prescribed Radicava.



## Stroke Rates Decreasing Among Men, Steady in Women

Although stroke incidence rates are dropping overall, new findings suggest that those decreases are only seen in men. In a study published online in *Neurology* (August 9), investigators tracked all incident strokes among a population of 1.3 million individuals at four specific periods in time: 1993-1994, 1999, 2005, and 2010. They found that rates of stroke incidence decreased over time in men but not in women. Additionally, rates were similar between women and men by 2010. The authors suggest continued research to better understand the pronounced decrease of stroke in men. ■

## More Headlines from NeurologyWire

### AstraZeneca and Takeda Ink \$400 Million Development Deal for Investigational Parkinson's Agent

AstraZeneca and Takeda Pharmaceutical Company Limited will jointly develop and commercialize an investigational alpha-synuclein antibody known as MEDI1341, currently being investigated for the treatment of Parkinson's disease. Differentiated by its high affinity, high selectivity, and reduced effector function (lower interaction with the immune system), MEDI1341 has the potential to achieve a better efficacy and safety profile than other alpha-synuclein antibodies, according to the two companies.

Under terms of the agreement, AstraZeneca will lead Phase I development while Takeda will lead future clinical development activities. Takeda will pay AstraZeneca up to \$400 million, including initial revenue in 2017 and development and sales milestones thereafter.

MEDI1341 is due to enter Phase I clinical trials later this year.

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