New Data For Teva AJOVY® (fremanezumab-vfrm) Injection and AUSTEDO® (deutetrabenazine) Tablets Included in Neurology
https://apnews.com/Business%20Wire/d9982fa7512e45a3be243ee31cde7717
AP TEL AVIV & PARSIPPANY, N.J.--(BUSINESS WIRE)--May 1, 2020

Teva Pharmaceuticals USA, Inc., an affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) today announced that new data for AJOVY ® (fremanezumab-vfrm) injection and AUSTEDO ® (deutetrabenazine) tablets have appeared in an online supplement to *Neurology*. The data includes 23 abstracts that highlight a diverse set of data evaluating the efficacy and safety of AJOVY and AUSTEDO.

The abstracts were originally planned for presentation at the recently cancelled 2020 American Academy of Neurology (AAN) annual meeting. In addition to the online supplement, the abstracts are also available through the AAN online abstracts website..

"We are pleased to have an opportunity to share this important data with the neurology community which build upon our understanding of the efficacy and safety of AJOVY and AUSTEDO across various patient populations, and further demonstrate Teva's commitment to the CNS space," said Denisa Hurtukova, MD, VP, Head of North America Medical Affairs. "Teva is committed to ongoing evaluation of these significant therapies to help physicians, healthcare providers and most importantly, patients, make informed decisions about their treatments."

The featured abstracts include new AJOVY and AUSTEDO data, including results from an open-label extension of the FOCUS study, a Phase IIIb study that evaluated the efficacy and safety of quarterly and monthly treatment with AJOVY compared to placebo in adult patients with migraine and documented inadequate response to 2-4 classes of prior preventive treatments. Another analysis using the FDA Adverse Events Reporting System (FAERS) provides patient and healthcare professional insight into the real-world experience with CGRP pathway-targeted therapies. In addition, new data is available from a long-term, open-label extension study which examined the safety of AUSTEDO at higher doses beyond the approved maximum dose to treat chorea associated with Huntington's disease, as well as the long-term experience with AUSTEDO in both younger and older patients with tardive dyskinesia.

The full list of Teva abstracts in the *Neurology* supplement includes:

AUSTEDO ® (deutetrabenazine) Tablets:

De Novo:

- Evaluation of the Safety of Deutetrabenazine at Higher Doses to Treat Chorea in Huntington's Disease
- Long-term Safety and Efficacy of Deutetrabenazine in Younger and Older Patients with Tardive Dyskinesia

Encore: Minimal Clinically Important Difference in AIMS Score Based on Clinical and Patient Global Impression of Change in Patients With Tardive Dyskinesia Treated With Deutetrabenazine

Effect of Deutetrabenazine on Metabolic Parameters in the Treatment of Tardive Dyskinesia

NOTE: For info on AJOVY go to above URL

About AUSTEDO ® (deutetrabenazine)

AUSTEDO ® is a vesicular monoamine transporter 2 (VMAT2) inhibitor approved by the U.S. Food and Drug Administration for the treatment of tardive dyskinesia in adults and for the treatment of chorea associated with Huntington's disease. Safety and effectiveness in pediatric patients have not been established.

AUSTEDO ® Indications and Usage

AUSTEDO ® is indicated for the treatment of chorea associated with Huntington's disease and for the treatment of tardive dyskinesia in adults.

Important Safety Information About AUSTEDO ®

Depression and Suicidality in Patients with Huntington's Disease: AUSTEDO®can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease. Balance the risks of depression and suicidality with the clinical need for treatment of chorea. Closely monitor patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior. Inform patients, their caregivers, and families of the risk of depression and suicidality and instruct them to report behaviors of concern promptly to the treating physician. Exercise caution when treating patients with a history of depression or prior suicide attempts or ideation. AUSTEDO ® is contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression.

Contraindications: AUSTEDO ® is contraindicated in patients with Huntington's disease who are suicidal, or have untreated or inadequately treated depression. AUSTEDO ® is also contraindicated in: patients with hepatic impairment; patients taking reserpine or within 20 days of discontinuing reserpine; patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of discontinuing MAOI therapy; and patients taking tetrabenazine (Xenazine ®) or valbenazine (Ingrezza ®).

Clinical Worsening and Adverse Events in Patients with Huntington's Disease:AUSTEDO®may cause a worsening in mood, cognition, rigidity, and functional capacity.Prescribers should periodically re-evaluate the need for AUSTEDO®in their patients by assessing the effect on chorea and possible adverse effects.

QTc Prolongation: Tetrabenazine, a closely related VMAT2 inhibitor, causes an increase in the corrected QT (QTc) interval. A clinically relevant QT prolongation may occur in some patients treated with AUSTEDO ® who are CYP2D6 poor metabolizers or are co-administered a strong CYP2D6 inhibitor. Dose reduction may be necessary. The use of AUSTEDO ® in combination with other drugs known to prolong QTc may result in clinically significant QT prolongations. For patients requiring AUSTEDO ® doses greater than 24 mg per day who are using AUSTEDO ® with other drugs known to prolong QTc, assess the QTc interval before and after increasing the dose of AUSTEDO ® or the other drugs. AUSTEDO ® should be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias.

Neuroleptic Malignant Syndrome (NMS),a potentially fatal symptom complex reported in association with drugs that reduce dopaminergic transmission, has been observed in patients receiving tetrabenazine. The risk may be increased by concomitant use of dopamine antagonists or antipsychotics. The management of NMS should include immediate discontinuation of AUSTEDO®; intensive symptomatic treatment and medical monitoring; and treatment of any concomitant serious medical problems.

Akathisia, Agitation, and Restlessness*:* AUSTEDO ® may increase the risk of akathisia, agitation, and restlessness. The risk of akathisia may be increased by concomitant use of dopamine antagonists or antipsychotics. If a patient develops akathisia, the AUSTEDO ® dose should be reduced; some patients may require discontinuation of therapy.

Parkinsonism*:* AUSTEDO ® may cause parkinsonism in patients with Huntington's disease or tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. The risk of parkinsonism may be increased by concomitant use of dopamine antagonists or antipsychotics. If a patient develops parkinsonism, the AUSTEDO ® dose should be reduced; some patients may require discontinuation of therapy.

Sedation and Somnolence*:* Sedation is a common dose-limiting adverse reaction of AUSTEDO ®. Patients should not perform activities requiring mental alertness, such as operating a motor vehicle or hazardous machinery, until they are on a maintenance dose of AUSTEDO ® and know how the drug affects them. Concomitant use of alcohol or other sedating drugs may have additive effects and worsen sedation and somnolence.

Hyperprolactinemia: Tetrabenazine elevates serum prolactin concentrations in humans. If there is a clinical suspicion of symptomatic hyperprolactinemia, appropriate laboratory testing should be done and consideration should be given to discontinuation of AUSTEDO ®.

Binding to Melanin-Containing Tissues*:* Deutetrabenazine or its metabolites bind to melanin-containing tissues and could accumulate in these tissues over time. Prescribers should be aware of the possibility of long-term ophthalmologic effects .

CYP2D6 Metabolism*:* In patients who are poor CYP2D6 metabolizers or are taking strong CYP2D6 inhibitors, the total daily dosage of AUSTEDO ® should not exceed 36 mg (maximum single dose of 18 mg).

Common Adverse Reactions: The most common adverse reactions for AUSTEDO ® (>8% and greater than placebo) in a controlled clinical study in patients with Huntington's disease were somnolence, diarrhea, dry mouth, and fatigue. The most common adverse reactions for AUSTEDO ® (4% and greater than placebo) in controlled clinical studies in patients with tardive dyskinesia were nasopharyngitis and insomnia. *JEM note:* nasopharyngitis: viral infection of the nose and throat.

Please see accompanying full Prescribing Information, including Boxed Warning.

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) has been developing and producing medicines to improve people's lives for more than a century. We are a global leader in generic and specialty medicines with a portfolio consisting of over 3,500 products in nearly every therapeutic area. Around 200 million people around the world take a Teva medicine every day, and are served by one of the largest and most complex supply chains in the pharmaceutical industry. Along with our established presence in generics, we have significant innovative research and operations supporting our growing portfolio of specialty and biopharmaceutical products. Learn more at www.tevapharm.com.

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