Sunovion to Present New Research and Data Analyses Supporting Use of Aptiom® (eslicarbazepine acetate) at the American Epilepsy Society (AES) 69th Annual Meeting

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MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc. (Sunovion) announced today that new clinical and health economics and outcomes research (HEOR) data for Aptiom™ (eslicarbazepine acetate) will be presented at the 69th Annual Meeting of the American Epilepsy Society (AES), taking place December 4 - 8, 2015 in Philadelphia. Noteworthy presentations include research highlighting the use of APTIOM as monotherapy and adjunctive treatment of partial-onset seizures.

In August 2015, Sunovion announced that the U.S. Food and Drug Administration (FDA) approved the use of APTIOM as monotherapy for the treatment of partial-onset seizures. APTIOM may be used as monotherapy in people who initiate treatment for the first time or convert from other antiepileptic drugs (AEDs) to APTIOM.

“We look forward to sharing new data about the clinical utility and value of APTIOM as an important treatment option,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer, Sunovion Pharmaceuticals Inc., and Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “Collectively, data from 14 presentations provide information that may assist healthcare providers as they seek to enhance clinical outcomes for people living with partial-onset seizures.

Sunovion-supported presentations during AES include:

Clinical Data Presentations:

- Poster 2.243 – Mortality in Phase III Studies of Adjunctive and Monotherapy Eslicarbazepine Acetate in Patients with Partial-Onset Seizures. Sunday, December 6, 2015, 8:00 a.m.-4:00 p.m. ET.
- Poster 2.254 – Efficacy and Safety of Eslicarbazepine Acetate Monotherapy (ESL) in Patients Previously Taking Carbamazepine (CBZ). Sunday, December 6, 2015, 8:00 a.m.-4:00 p.m. ET.
- Poster 1.186 – Incidence of Treatment Emergent Adverse Events in Three Phase III Studies of Adjunctive Eslicarbazepine Acetate, in Patients Taking or Not Taking Lamotrigine at Baseline. Saturday, December 5, 2015, 12:00 p.m – 6:00 p.m ET.
- Poster 2.252 – Tolerability of Adjunctive Eslicarbazepine Acetate in Elderly Patients with Epilepsy: An Exploratory Post-Hoc Analysis of Three Phase III Studies. Sunday, December 6, 2015, 8:00 a.m.-4:00 p.m. ET.

HEOR Presentations:

- Poster 1.182 – Quality of Life Improvement among patients with Refractory Partial-Onset Seizures: A Clinical Trial Analysis of Patients Who Responded to Eslicarbazepine Acetate Monotherapy. Saturday, December 5, 2015, 12:00 p.m – 6:00 p.m ET.
- Poster 2.249 – Change in Depressive Symptoms among Patients with Refractory Partial-Onset Seizures Treated with Eslicarbazepine Acetate Monotherapy: A Pooled Analysis of Clinical Trials. Sunday, December 6, 2015, 8:00 a.m.-4:00 p.m. ET.
- Poster 2.282 – The Association Between Antiepileptic Drug Pill Burden at Monotherapy Initiation and Epilepsy-Related Hospital Admissions and Emergency Department Visits in the US. Sunday, December 6, 2015, 8:00 a.m.-4:00 p.m. ET.

About Aptiom® (eslicarbazepine acetate)

APTIOM is the latest member of the dibenzazepine carboxamide family of antiepileptic drugs (AEDs), an established class of medicines. APTIOM is the only exclusively once-daily, non-extended release AED now FDA-approved for use as monotherapy or adjunctive therapy for partial-onset seizures. The precise mechanism(s) by which eslicarbazepine acetate works is not fully understood. Eslicarbazepine acetate is thought to be a voltage-gated sodium channel blocker.

The initial research and development of eslicarbazepine acetate was performed by BIAL-Portela & Cia, S.A. (BIAL), a privately held Portuguese research-based pharmaceutical company. Subsequently, Sunovion acquired the rights under an exclusive license to further develop and commercialize eslicarbazepine acetate in the United States and Canada markets from BIAL. BIAL gained approval for eslicarbazepine acetate from the European Medicines Agency on April 21, 2009 as adjunctive therapy in adult patients with partial-onset seizures with or without secondary generalization. In Europe, the product is marketed under the trade name Zebrinix®. APTIOM is approved for use as monotherapy in the treatment of partial-onset seizures in patients with epilepsy who are not satisfactorily controlled with conventional therapy.

About Epilepsy and Partial-Onset Seizures

Epilepsy is the fourth most common neurological condition, and one in 26 people in the U.S. will develop epilepsy in his or her lifetime.1 Epilepsy manifests as unprovoked seizures, which are caused by abnormal firing of impulses from nerve cells in the brain.2 Partial-onset seizures, the most common type of seizure, are characterized by bursts of electrical activity that are initially focused in specific areas of the brain and may become more widespread, with symptoms varying according to the affected area.3 The unpredictable nature of seizures may have a significant impact on those with epilepsy. Reducing the frequency of seizures may lessen the burden of epilepsy.4 Up to approximately one-third of people living with epilepsy still unable to control seizures, there continues to be a need for new therapies.4 Up to 40 percent of people living with epilepsy do not respond to the first or second monotherapy5, and approximately 36 percent fail to achieve adequate control of seizures despite the use of two or more antiepileptic medications.6

Please see Important Safety Information below.

INDICATION:

Aptiom® (eslicarbazepine acetate) is a prescription medicine used alone or with other medicines to treat partial-onset seizures.

IMPORTANT SAFETY INFORMATION:

Do not take APTIOM if you are allergic to eslicarbazepine acetate, any of the other ingredients in APTIOM, or oxcarbazepine.

Suicidal behavior and ideation: APTIOM may cause suicidal thoughts or actions, depression, or mood problems. Call your doctor or right away if you experience these or any other effects or reactions: thoughts about suicide or dying; attempting to commit suicide; new or worse depression, anxiety, or irritability; feeling agitated or restless; panic attacks; trouble sleeping (insomnia); acting aggressive, being angry or violent; acting on dangerous impulses; an extreme increase in activity and talking (mania); or other unusual changes in behavior or mood.

Allergic reactions: APTIOM may cause serious skin rash or other serious allergic reactions that may affect organs or other parts of your body like the liver or blood cells. You may or may not have a rash with these types of reactions. Call your doctor right away if you experience any of the following symptoms: swelling of the face, eyes, lips, or tongue; trouble swallowing or breathing; hives; fever, swollen glands, or sore throat that do not go away or come and go; painful sores in the mouth or around your eyes, yellowing of the skin or eyes; unusual bruising or bleeding; severe fatigue or weakness; severe muscle pain; or frequent infections or infections that do not go away.

Low salt (sodium) levels in the blood: APTIOM may cause the level of sodium in your blood to be low. Symptoms may include nausea, tiredness, lack of energy, irritability, confusion, muscle weakness or muscle spasm, or more frequent or more severe seizures.
Nervous system problems: APTIOM may cause problems that can affect your nervous system, including dizziness, sleepiness, vision problems, trouble concentrating, and difficulties with coordination and balance. APTIOM may slow your thinking or motor skills. Do not drive or operate heavy machinery until you know how APTIOM affects you.

Liver problems: APTIOM may cause problems that can affect your liver. Symptoms of liver problems include yellowing of your skin or the whites of your eyes, nausea or vomiting, loss of appetite, stomach pain, or dark urine.

Most common adverse reactions: The most common side effects in patients taking APTIOM include dizziness, sleepiness, nausea, headache, double vision, vomiting, feeling tired, problems with coordination, blurred vision, and shakiness.

Drug interactions: Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking APTIOM with certain other medicines may cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider. Especially tell your healthcare provider if you take oxcarbazepine, carbamazepine, phenobarbital, phenytoin, primidone, clonazepam, omeprazole, simvastatin, rosuvastatin, or birth control medicine.

Discontinuation: Do not stop taking APTIOM without first talking to your healthcare provider. Stopping APTIOM suddenly can cause serious problems.

Pregnancy and lactation: APTIOM may cause your birth control medicine to be less effective. Talk to your healthcare provider about the best birth control method to use. APTIOM may harm your unborn baby. APTIOM passes into breast milk. Tell your healthcare provider if you are pregnant or plan to become pregnant, or are breast feeding or plan to breastfeed. You and your healthcare provider will decide if you should take APTIOM. If you become pregnant while taking APTIOM, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy. You can enroll in this registry by calling 1-888-233-2334.

Get medical help right away if you have any of the symptoms listed above.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. For more information, please see the APTIOM Medication Guide and Full Prescribing Information at www.APTIOM.com.© 2015 Sunovion Pharmaceuticals Inc.

References


Language: English

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Links: