Sunovion to Present Data Analyses Supporting Use of Aptiom® (eslicarbazepine acetate) at the 68th American Academy of Neurology (AAN) Annual Meeting

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Terms:

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MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc. (Sunovion) will present clinical and health economics and outcomes research (HEOR) data at the 68th American Academy of Neurology (AAN) Annual Meeting, taking place April 15-21, 2016 in Vancouver, Canada. Several presentations highlight the use of APTIOM® as monotherapy and adjunctive therapy for the treatment of partial-onset seizures.

“A key priority at Sunovion is our commitment to people with central nervous system disorders, including epilepsy,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer, Sunovion Pharmaceuticals Inc. “We are pleased to share findings at AAN that help advance the understanding of epilepsy and the clinical utility of APTIOM® in treating partial-onset seizures.”

Sunovion-supported presentations during AAN include:

HEOR Presentations:
- Poster 2.023 - Assessment of Eslicarbazepine Acetate Monotherapy vs. Other Anti-Epileptic Drugs for Refractory Partial-Onset Seizures: Results of a Network Meta-Analysis Using Historical Controls Trial. Sunday, April 17, 2016, 8:30 a.m. PT.
- Poster 2.028 - Patients Treated with Eslicarbazepine Acetate Monotherapy Show Quality of Life Improvement. Sunday, April 17, 2016, 8:30 a.m. PT.
- Poster 2.031 - Eslicarbazepine Acetate Associated with Reduced Seizure Severity in Addition to Reduced Seizure Frequency. Sunday, April 17, 2016, 8:30 a.m. PT.
- Poster 4.205 - The Association of Adherence with Health-Related Quality of Life by Age Group Among Patients with Epilepsy. Tuesday, April 19, 2016, 8:30 a.m. PT.
- Poster 5.009 - Comparing Anti-Epileptic Drug Preferences Between Neurologists and Patients: Results from a National Survey and Discrete Choice Experiment. Wednesday, April 20, 2016, 8:30 a.m. PT. This presentation also will be included in the “Practical Approaches to Narrowing the Epilepsy Treatment Gap - Integrated Neuroscience” session on Thursday, April 21, 2016 from 3:00 p.m. to 3:30 p.m. PT as presentation 010.

Clinical Data Presentations:
- Poster 2.025 - Use of Pharmacokinetic-Pharmacodynamic Modeling and Simulations to Predict Efficacy Outcomes with Eslicarbazepine Acetate 800mg Once-Daily as Monotherapy. Sunday, April 17, 2016, 8:30 a.m. PT.
- Poster 2.030 - Markers of Bone Turnover and Lipid Metabolism During Eslicarbazepine Acetate Monotherapy in Patients Taking or Not Taking Enzyme-Inducing Antiepileptic Drugs at Baseline. Sunday, April 17, 2016, 8:30 a.m. PT.
- Poster 2.029 - Efficacy and Safety of Eslicarbazepine Acetate Monotherapy in Patients Converting from Carbamazepine. Sunday, April 17, 2016, 8:30 a.m. PT.
- Poster 2.035 - Tolerability of Adjunctive Eslicarbazepine Acetate in Elderly Patients with Partial-Onset Seizures: An Exploratory Post-Hoc Analysis of Three Phase III Studies. Sunday, April 17, 2016, 8:30 a.m. PT.
- Poster 2.058 - Mortality in Phase III Studies of Adjunctive and Monotherapy Eslicarbazepine Acetate in Patients with Partial-Onset Seizures. Sunday, April 17, 2016, 8:30 a.m. PT.

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 FDA-approved for use as monotherapy or adjunctive therapy for partial-onset seizures. The precise mechanism(s) by which eslicarbazepine acetate, the primary active metabolite of APTIOM, exerts anticonvulsant activity is unknown but is thought to involve inhibition of voltage-gated sodium channels. APTIOM can be taken whole or crushed, with or without food. APTIOM is not classified as a controlled substance by the FDA.

The initial research and development of eslicarbazepine acetate was performed by BIAL-Portela & Ca, 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 Commission 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 Zebinix®. APTIOM® is approved in Canada for use as adjunctive therapy 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 areas.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 With approximately one-third of people living with epilepsy still unable to control seizures, there continues to be a need for new therapies.5 Up to 40 percent of people living with epilepsy do not respond to the first or second monotherapy,5 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 mood problems: APTIOM may cause suicidal thoughts or actions, depression, or mood problems. Call your doctor right away if you experience any of these or any other reactions or effects: 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 aggressively; 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 spasms, or more frequent or more severe seizures. Some medicines can also cause low sodium in your blood. Be sure to tell your healthcare provider about all other medicines that you are taking.

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 telling your healthcare provider. Especially tell your healthcare provider if you take oxcarbazepine, carbamazepine, phenobarbital, phenytoin, primidone, clobazam, 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 method 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 breastfeeding 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 (11) or call 1-800-FDA-1088.

For more information, please see the APTIOM Medication Guide (4) and Full Prescribing Information (4).

About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion Pharmaceuticals Inc. is a global biopharmaceutical company focused on the innovative application of science to help people with serious medical conditions. Sunovion’s spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. The Company has charted new paths to life-transforming treatments that reflect ongoing investments in research and development and an unwavering commitment to support people with psychiatric, neurological, and respiratory conditions. Sunovion’s track record of discovery, development and commercialization of important therapies has included Brovana® (afomeronol tartrate), Latuda® (lurasidone HCl), and most recently Aptiom® (eslicarbazepine acetate).

Headquartered in Marlborough, Mass., Sunovion is an indirect, wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. Sunovion Pharmaceuticals Europe Ltd., based in London, England, and Sunovion Pharmaceuticals Canada, Inc., based in Mississauga, Ontario, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the Company’s web sites: www.sunovion.com, www.sunovion.ca and www.sunovion.ca. Connect with Sunovion on Twitter @Sunovion(9) and LinkedIn (10).

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is a top-ten listed pharmaceutical company in Japan. Sumitomo Dainippon Pharma aims to produce innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd. and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com (11).

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For a copy of this release, visit Sunovion’s web site at www.sunovion.com (12).


Language:

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