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News Release

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Sunovion Pharmaceuticals Inc. Announces FDA Acceptance for Review of Supplemental New Drug Application for the Use of Aptiom® (eslicarbazepine acetate) as Monotherapy Treatment for Partial-Onset Seizures

Marlborough, Mass., January 7, 2015 – Sunovion Pharmaceuticals Inc. (Sunovion) announced today the U.S. Food and Drug Administration (FDA) has accepted for review a supplemental New Drug Application (sNDA) for the use of Aptiom® (eslicarbazepine acetate) as monotherapy treatment of partial-onset seizures. The sNDA was submitted to the FDA by Sunovion on October 29, 2014 and included data from two Phase 3 double-blind, historical-controlled, multi-center randomized trials involving patients with partial-onset seizures.

"APTIOM has been well-received for use as an adjunctive treatment in partial-onset seizures," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer, Sunovion. "We are pleased with the FDA's acceptance of the filing for review and look forward to potential approval of APTIOM as monotherapy with once-daily dosing for patients with this complex neurological disorder."

The two trials (Studies 093-046 and 093-045) were designed identically to evaluate the safety and efficacy of APTIOM (1,600 mg/day or 1,200 mg/day) as monotherapy treatment for partial-onset seizures in patients 16 years of age or older whose seizures were not well-controlled by other antiepileptic drugs (AEDs). All patients in Study 093-045 were evaluated in North America. Study 093-046 included approximately 25 percent of patients from the United States and approximately 75 percent from four European countries. The primary endpoint for both studies was the proportion of patients with partial-onset seizures meeting pre-defined exit criteria (signifying worsening seizure control) 16 weeks post-titration of APTIOM, in comparison to historical controls.

APTIOM is approved for use as adjunctive treatment of partial-onset seizures. APTIOM was launched in the United States on April 7, 2014. APTIOM is not approved for use as monotherapy for partial-onset seizures.

About Partial-Onset Seizures

Epilepsy is characterized by abnormal firing of impulses from nerve cells in the brain.[i] In partial-onset seizures, these bursts of electrical activity are initially focused in specific areas of the brain, but may become more widespread, with symptoms varying according to the affected areas.[ii,iii] The unpredictable nature of seizures can have a significant impact on those with epilepsy, affecting a number of areas of daily living, including education, employment, driving and recreation. Reducing the frequency of seizures can greatly lessen the burden of epilepsy.[iv] With approximately one-third of people living with epilepsy still unable to control seizures, there continues to be a need for new therapies.[v]

About Aptiom® (eslicarbazepine acetate)

APTIOM, a voltage-gated sodium channel inhibitor, is a prescription medicine approved for use as adjunctive treatment of partial-onset seizures, and is available in four tablet strengths (200 mg, 400 mg, 600 mg, and 800 mg), which 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 Canadian markets from BIAL. BIAL gained approved 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®.

Please see Important Safety Information below.

INDICATION:

Aptiom® (eslicarbazepine acetate) is a prescription medicine used 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 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 spasms, 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, 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 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 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 or call 1-800-FDA-1088.

For more information, please see the APTIOM Medication Guide and Full Prescribing Information at www.APTIOM.com.

About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion is a leading pharmaceutical company dedicated to discovering, developing and commercializing therapeutic products that advance the science of medicine in the Psychiatry, Neurology and Respiratory disease areas to improve the lives of patients and their families.

Sunovion, an indirect, wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at www.sunovion.com.

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

APTIOM is used under license from BIAL.

Sunovion Pharmaceuticals Inc. is a U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd.

For a copy of this release, visit Sunovion's web site at www.sunovion.com

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[ii] Epilepsy Foundation. "Partial Seizures." Accessed 5 September 2013. <"http://www.epilepsyfoundation.org/aboutepilepsy/seizures/partialseizures/index.cfm>

[iii] Dartmouth Medical School. "Disorders of the Central Nervous System: A Primer (Chapter 22: Epilepsy)." Accessed 5 September 2013. <http://www.dartmouth.edu/~*dons*/part_3/chapter_22.html>

[iv] Institute of Medicine (IOM). 2012. "Epilepsy across the spectrum: Promoting health and understanding." Washington, DC: The National Academies Press.

[v] Brodie MJ, Barry SJE, Bamagous GA, Norrie JD, Kwan P. Patterns of treatment response in newly diagnosed epilepsy. *Neurology*. 2012;78:1548-1554.