

News Release

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Sunovion Pharmaceuticals Inc. Presents Positive Results From Two Phase 3 Studies of Once-Daily Aptiom® (eslicarbazepine acetate) as Monotherapy Treatment for Partial-Onset Seizures

- **Patients with partial-onset seizures poorly-controlled on 1-2 AEDs who converted to APTIOM monotherapy had a further 30.9%-47.5% reduction in seizure frequency**
- **Supplemental new drug application planned for spring 2014**

Marlborough, Mass., December 9, 2013 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced results from two Phase 3 trials (Studies 093-046 and 093-045) of Aptiom® (eslicarbazepine acetate) as a monotherapy treatment in patients with partial-onset seizures. Study results showed that APTIOM demonstrated seizure control rates superior to historical controls in patients with partial-onset seizures who were not well-controlled by current antiepileptic drugs (AEDs). These data were presented at the 67th Annual Meeting of the American Epilepsy Society (AES) taking place December 6-10 in Washington, D.C.

APTIOM was approved on November 8, 2013 by the U.S. Food and Drug Administration (FDA) as adjunctive treatment of partial-onset seizures. The efficacy and safety of APTIOM as monotherapy treatment for patients with partial-onset seizures has not been evaluated by the FDA. APTIOM is not approved for use as monotherapy.

“We are pleased with the data from these Phase 3 trials investigating APTIOM as monotherapy treatment for adult patients with partial-onset seizures,” said Fred Grossman, D.O., FAPA, Senior Vice President, Clinical Development and Medical Affairs at Sunovion. “Based on the results of the data presented today, Sunovion plans to seek approval of APTIOM as monotherapy treatment for patients with partial-onset seizures.”

The objective of the studies was to evaluate the efficacy and safety of APTIOM as monotherapy treatment for partial-onset seizures in patients who were not well-controlled by current AEDs. 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.

Treatment was considered effective if the upper limit of the 95% confidence interval (CI) for the exit rate (estimated using Kaplan-Meier methods) was lower than the lower limit of the pre-specified prediction interval (i.e. 65.3% for a single study and 72.2% for two independent studies), based on the historical controls.

Key Safety and Efficacy Results

The two completed Phase 3 APTIOM monotherapy trials (Studies 093-046 and 093-045) met their primary endpoints for both doses in each study. In Study 093-046, the exit rates (estimated using Kaplan-Meier methods) were 15.6% (95% CI: 8.1 to 28.7%) for the 1,200 mg dose arm and 12.8% (95% CI: 7.5 to 21.5%) for the 1,600 mg dose arm. In Study 093-045, the exit rates were 44.4% (95% CI: 32.5 to 58.3%) for the 1,200 mg dose arm and 28.7% (95% CI: 21.2 to 38.1%) for the 1,600 mg dose arm. For these studies, exit rates were lower than the historical control thresholds of 65.3% (for a single study) and 72.2% (for two independent studies). A pre-specified secondary endpoint of change from baseline in standardized seizure frequency during the double-blind treatment period demonstrated a median reduction in seizure frequency of 36.1% and 47.5% in the 1,200 mg and 1,600 mg dose arms of Study 093-046, respectively, and 30.9% and 41.5% median reduction in seizure frequency in the 1,200 mg and 1,600 mg dose arms of Study 093-045, respectively.

APTIOM was well-tolerated in both monotherapy studies, with adverse events generally similar to those observed in prior placebo-controlled adjunctive trials. The most common treatment-emergent adverse events (TEAEs) in the two studies were dizziness, headache, fatigue, somnolence, nausea and nasopharyngitis, occurring in $\geq 5\%$ of patients in both Studies 093-046 and 093-045. Additional TEAEs reported in Study 093-046 included back pain, complex partial seizures, insomnia, anxiety and influenza. Additional TEAEs reported in Study 093-045 included back pain, partial seizures with secondary generalization, vomiting and blurred vision. In Study 093-046, discontinuations due to TEAEs were reported in 3.4% and 12.3% of patients in the 1,200 mg and 1,600 mg dose arms, respectively. Discontinuations due to TEAEs were reported in 12.3% and 18.0% of subjects in the 1,200 mg and 1,600 mg dose arms, respectively, of Study 093-045. The TEAEs that most frequently led to discontinuation seen in at least 2% of patients were complex partial seizures (2.3%) in Study 093-046 and hyponatremia in Study 093-045 (2.1%).

Study Design

Studies 093-046 and 093-045 were two Phase 3, double-blind, historical-controlled, multicenter randomized trials with identical study designs, which evaluated APTIOM monotherapy for treating partial-onset seizures. Study 093-046, a global study, included 172 patients across 41 study centers in five countries and included 25% of patients from the United States. Study 093-045 included 193 patients from

67 study centers across North America and is the first historically controlled epilepsy monotherapy study conducted solely in North America.

In both studies, patients with partial-onset seizures 16 years of age or older who were not well-controlled (\geq four partial-onset seizures in the eight weeks prior to screening and no four week seizure-free period) with one to two AEDs were gradually converted to monotherapy treatment with APTIOM and randomized 2:1 to receive APTIOM 1,600 mg once-daily (n=114 in Study 093-046; n=128 in Study 093-045) or APTIOM 1,200 mg once-daily (n=58 in Study 093-046; n=65 in Study 093-045). Patients with partial-onset seizures were using one AED (64.5% in Study 093-046 and 73.6% in Study 093-045) or two AEDs (35.5% in Study 093-046 and 26.4% in Study 093-045).

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.^{iv} 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

APTIOM, a voltage-gated sodium channel inhibitor, is a prescription medicine approved for use as adjunctive treatment of partial-onset seizures.

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 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 and the agent is currently marketed under the trade name Zebinix[®] in Europe under a license and co-promotion agreement with Eisai Europe Limited, a European subsidiary of Eisai Co., Ltd.

Please see Important Safety Information below.

Sunovion Support[™], the Sunovion patient assistance program, may help eligible patients receive APTIOM at no charge to the patient when it becomes available. Following the launch of APTIOM, more information on this program, including eligibility criteria, may be found at www.SunovionSupport.com.

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.

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.

APTIOM may cause serious skin rash or other serious allergic reactions, which may affect organs or other parts of your body like the liver or blood cells. Some symptoms may include: swelling of the face, eyes, lips or tongue, trouble swallowing or breathing, yellowing of the skin or eyes or severe fatigue or weakness.

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.

APTIOM may cause problems that can affect your nervous system including dizziness, sleepiness, vision problems 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.

Do not stop taking APTIOM without first talking to your healthcare provider. Stopping APTIOM suddenly can cause serious 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 and nausea or vomiting.

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.

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.

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. Sunovion's drug development program, together with its corporate development and licensing efforts, has yielded a portfolio of pharmaceutical products including Aptiom[®] (eslicarbazepine acetate), Latuda[®] (lurasidone HCl) tablets, Lunesta[®] (eszopiclone) tablets, Xopenex[®] (levalbuterol HCl) inhalation solution, Xopenex HFA[®] (levalbuterol tartrate) inhalation aerosol, Brovana[®] (arformoterol tartrate) inhalation solution, Omnaris[®] (ciclesonide) nasal spray, Zetonna[®] (ciclesonide) nasal aerosol and Alvesco[®] (ciclesonide) inhalation aerosol.

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

About Dainippon Sumitomo Pharma Co., Ltd. (DSP)

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

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ⁱ National Institutes of Health. "NINDS Epilepsy Information Page." Accessed 5 September 2013. <<http://www.ninds.nih.gov/disorders/epilepsy/epilepsy.htm>>.

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} IOM (Institute of Medicine). 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.