

News Release

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Once-Daily Aptiom[®] (eslicarbazepine acetate) for the Adjunctive Treatment of Partial-Onset Seizures Now Available in U.S. Pharmacies

Marlborough, Mass., April 7, 2014 – Sunovion Pharmaceuticals Inc. (Sunovion) announced that Aptiom[®] (eslicarbazepine acetate), a once-daily antiepileptic drug (AED) indicated for use as adjunctive treatment of partial-onset seizures, is now available by prescription in pharmacies across the United States. APTIOM, a voltage-gated sodium channel blocker, is a new chemical entity approved by the U.S. Food and Drug Administration (FDA) on November 8, 2013, 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.

“Epilepsy is a serious condition that not only affects the people who suffer from seizures, but also their family, caregivers and friends,” said Michael R. Sperling, M.D., Professor of Neurology at Thomas Jefferson University and director of the Jefferson Comprehensive Epilepsy Center in Philadelphia, Pennsylvania. “Approximately one-third of those with epilepsy still have inadequate seizure control despite treatment, so we need new therapies. APTIOM is a welcome addition to our therapeutic toolkit that may help some patients.”

The FDA approval of APTIOM for the adjunctive treatment of partial-onset seizures was based on three pivotal Phase 3 randomized, double-blind, placebo-controlled trials. Results demonstrated that patients treated with APTIOM experienced statistically significant reductions in standardized seizure frequency and significantly more APTIOM-treated patients demonstrated seizure frequency reduction of 50 percent or more from baseline versus placebo. APTIOM was shown to have a favorable safety profile with a low incidence of severe adverse events when used as adjunctive therapy in adult patients with partial-onset seizures. The most common side effects in patients taking APTIOM included dizziness, sleepiness, nausea, headache, double vision, vomiting, feeling tired, vertigo, problems with coordination, blurred vision and shakiness.

“APTIOM offers healthcare providers and patients living with partial-onset seizures a new adjunctive treatment option with once-daily dosing,” said Rick Russell, Executive Vice President and Chief Commercial Officer at Sunovion. “The availability of APTIOM is a significant milestone for Sunovion. APTIOM not only marks our entry into the epilepsy therapeutic area, but also reinforces our commitment to improving the lives of people living with CNS disorders.”

Sunovion Support™, a prescription assistance program, may help people who are eligible to receive their medication at no cost. More information about this program, including eligibility criteria, may be found at www.SunovionSupport.com.

About Partial-Onset Seizures

Epilepsy is one of the most common neurological disorders and affects nearly 2.2 million people in the United States.ⁱ Epilepsy is characterized by abnormal firing of impulses from nerve cells in the brain.ⁱⁱ Partial-onset seizures are the most prevalent seizure type, accounting for 60 percent of new epilepsy diagnoses.ⁱⁱⁱ In partial-onset seizures, 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.^{iv,v} 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.ⁱ Reducing the frequency of seizures can greatly lessen the burden of epilepsy.ⁱ

About APTIOM

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

The safety and efficacy of APTIOM was established in three Phase 3 randomized, double-blind, placebo-controlled trials of more than 1,400 people living with partial-onset seizures inadequately controlled by one to three concomitant AEDs (including carbamazepine, lamotrigine, valproic acid and levetiracetam). These studies showed that treatment with APTIOM demonstrated statistically significant reductions in standardized seizure frequency versus placebo, and significantly more APTIOM-treated patients experienced seizure frequency reduction of 50 percent or more from baseline (41 percent compared to 22 percent for placebo-treated patients). The most common side effects in patients taking APTIOM included dizziness, sleepiness, nausea, headache, double vision, vomiting, feeling tired, problems with coordination, blurred vision and shakiness.

Sunovion acquired the rights under an exclusive license to further develop and commercialize eslicarbazepine acetate in the United States and Canadian markets from BIAL-Portela & Ca, S.A. (BIAL), a privately held Portuguese research-based pharmaceutical company. BIAL conducted the initial research and development of eslicarbazepine acetate and, in April 2009, received approval from the European Commission for the use of eslicarbazepine acetate 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](#).

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 Daiinippon Sumitomo Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at www.sunovion.com.

About Daiinippon 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 Daiinippon 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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APTIOM is under license from BIAL. 

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

ⁱⁱ National Institutes of Health (NIH). "NINDS Epilepsy Information Page" Accessed 3 March 2014. <http://www.ninds.nih.gov/disorders/epilepsy/epilepsy.htm>

ⁱⁱⁱ Hauser WA, Annegers JF, Kurland LT. "Prevalence of Epilepsy in Rochester, Minnesota: 1940-1980." *Epilepsia*. 1991;32:429-445.

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- ^{iv} Epilepsy Foundation. "Complex Partial Seizures." Accessed 2 April 2014. <<http://www.epilepsy.com/learn/types-seizures/complex-partial-seizures>>
- ^v Dartmouth Medical School. "Disorders of the Central Nervous System: A Primer (Chapter 22: Epilepsy)." Accessed 3 March 2014. <http://www.dartmouth.edu/~dons/part_3/chapter_22.html>