

News Release

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Sunovion’s Aptiom® (eslicarbazepine acetate) Receives FDA Approval for Expanded Indication to Treat Partial-Onset Seizures in Children and Adolescents 4 Years of Age and Older

– APTIOM provides an important new treatment option for children and adolescents four to 17 years of age with partial-onset seizures –

– APTIOM is a once-daily, immediate release antiepileptic drug that can be taken whole or crushed, with or without food –

Marlborough, Mass., September 14, 2017 – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) today announced that the U.S. Food and Drug Administration (FDA) approved the supplemental New Drug Application (sNDA) to expand the indication for its antiepileptic drug (AED) Aptiom® (eslicarbazepine acetate) to include treatment of partial-onset seizures (POS) in children and adolescents four to 17 years of age.

APTIOM is also approved in the U.S. for the treatment of POS in adults. APTIOM is a once-daily, immediate release AED that can be taken whole or crushed, with or without food.

“Despite being the most common seizure type in patients with epilepsy, there continues to be a critical need for new therapeutic options for partial-onset seizures, especially for children and adolescents,” said Steven Wolf, M.D., Director of Pediatric Epilepsy and Associate Professor of Neurology at Mount Sinai Health System. “The unpredictable nature of seizures can be disruptive in the lives of these young people and their families, friends and community. It is important that physicians have additional treatment options that address patient needs.”

The approval to expand APTIOM’s indication to include children four years of age and older is based on FDA guidance that permits the extrapolation of data to support pediatric use. The safety and efficacy of APTIOM as monotherapy and adjunctive therapy for the treatment of POS in adults was

established in five multicenter, randomized, controlled clinical trials. Data from three clinical trials conducted by Sunovion's partner BIAL also supported the safety and tolerability of APTIOM for the treatment of POS in pediatric patients. Pharmacokinetic analyses of adult and pediatric data supported the proposed dosing regimen in the pediatric population.

“Epilepsy can be a challenging condition to manage. An estimated one in three people living with epilepsy are unable to control their seizures through available treatments,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “Treatment decisions must be based on individual needs, and we are pleased to offer APTIOM to people, including children and adolescents, who may need a once-daily treatment option for partial-onset seizures that can be taken whole or crushed, with or without food.”

“We are pleased that the benefits of treatment with APTIOM for children and adolescents four years of age and older with partial-onset seizures have now been established,” said David Frawley, Executive Vice President and Chief Commercial Officer at Sunovion. “This approval further emphasizes Sunovion's commitment to people living with epilepsy and to advancing the treatment of partial-onset seizures.”

Anyone seeking medical information, patient assistance and other information can access Sunovion Answers by calling 1-844-427-8466 Monday through Friday from 8:00 a.m. to 8:00 p.m. ET.

About Aptiom® (eslicarbazepine acetate)

APTIOM is a member of the dibenzazepine carboxamide family of antiepileptic drugs (AEDs), an established class of medicines. APTIOM is a once-daily, immediate release AED FDA-approved for the treatment of partial-onset seizures in adults, children and adolescents (four years of age and older). The precise mechanism(s) by which eslicarbazepine, 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, a privately held Portuguese research-based pharmaceutical company. Sunovion acquired the rights to eslicarbazepine acetate in the United States and Canada markets under an exclusive license from BIAL. APTIOM is approved in Canada for use as adjunctive therapy in the treatment of partial-onset seizures in adults with epilepsy who are not satisfactorily controlled with conventional therapy. BIAL gained approval for eslicarbazepine acetate from the European Medicines Agency in April 2009, as adjunctive therapy in adult patients with partial-onset seizures with or without secondary generalization; in December 2016, as adjunctive treatment for patients above six years of age with

partial-onset seizures with or without secondary generalization; and in March 2017, as monotherapy in the treatment of partial-onset seizures, with or without secondary generalization, in adults with newly diagnosed epilepsy. In Europe, the product is marketed under the trade name Zebinix®.

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 In the U.S., approximately 3.4 million people are living with active epilepsy, including approximately 470,000 children 17 years of age or younger.² Epilepsy manifests as unprovoked seizures, which are caused by abnormal firing of impulses from nerve cells in the brain.³ Partial-onset seizures 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.⁴ 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. 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,⁶ and approximately 36 percent fail to achieve adequate control of seizures despite the use of two or more antiepileptic medications.⁷

Please see Important Safety Information below.

INDICATION:

Aptiom® (eslicarbazepine acetate) is a prescription medicine to treat partial-onset seizures in patients 4 years of age and older.

IMPORTANT SAFETY INFORMATION:

It is not known if APTIOM is safe and effective in children under 4 years of age.

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

Suicidal behavior and ideation: Antiepileptic drugs, including APTIOM, may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call your doctor right away if you have any of the following symptoms, especially if they are new, worse, or worry you: 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. Some medicines can also cause low sodium in your blood. Be sure to tell your health care provider about all the 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 adult patients taking APTIOM include dizziness, sleepiness, nausea, headache, double vision, vomiting, feeling tired, problems with coordination, blurred vision, and shakiness. Side effects seen in pediatric patients are similar to those seen in adult patients.

Drug interactions: Tell your health care 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 health care provider.** Especially tell your health care 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 health care 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 health care provider about the best birth control method to use. APTIOM may harm your unborn baby. APTIOM passes into breast milk. Tell your health care provider if you are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. You and your health care provider will decide if you should take APTIOM. If you become pregnant while taking APTIOM, talk to your health care 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 global biopharmaceutical company focused on the innovative application of science and medicine to help people with serious medical conditions. Sunovion's vision is to lead the way to a healthier world. The company's spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. With patients at the center of everything it does, Sunovion 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/or commercialization of important therapies has included Utibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder, Brovana® (arformoterol tartrate) inhalation solution, Latuda® (lurasidone HCl) and 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.eu and www.sunovion.ca. Connect with Sunovion on [Twitter](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).


About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan operating globally in major pharmaceutical markets, including Japan, the United States, China and the European Union. Sumitomo Dainippon Pharma aims to create 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 6,500 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

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