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News Release

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Sunovion Submits Supplemental New Drug Application to FDA for Use of APTIOM® (eslicarbazepine acetate) for the Treatment of Partial-Onset Seizures in Children 4 Years of Age and Older

- If approved, APTIOM® would provide an important new monotherapy or adjunctive therapy treatment option for individuals as early as four years of age who experience partial-onset seizures -

Marlborough, Mass., March 13, 2017 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that it has submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) to expand the indication for its antiepileptic drug (AED) APTIOM® (eslicarbazepine acetate) to include use as monotherapy or adjunctive therapy for the treatment of partial-onset seizures (POS) in children four years of age and older.

APTIOM is the only exclusively once-daily, immediate release antiepileptic drug (AED) that is FDA-approved for use as monotherapy or adjunctive therapy for POS in adults. The treatment can be taken whole or crushed, with or without food, and can be administered with flexible dosing based on patient response and tolerability.

"Sunovion is committed to the continued development of APTIOM to bring this treatment option to as many people as possible who experience partial-onset seizures," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. "There is a significant need for new therapeutic options for children and adolescents with partial-onset seizures. Approximately one-third of people living with epilepsy are unable to control their seizures through available treatments, including the approximately 60 percent of people with epilepsy who have partial-onset seizures."

Sunovion is seeking an expansion of APTIOM's indication for adjunctive therapy and monotherapy in adults to include children four years of age and older based on FDA guidance regarding the use of extrapolation of data to support an application. 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. All trials met the pre-specified primary endpoints agreed upon with the FDA. In the sNDA submission, Sunovion will also include data from three clinical trials conducted by our partner BIAL-Portela & C.[a], S.A. (BIAL), which support the safety and tolerability of APTIOM for the treatment of POS in pediatric patients, along with pharmacokinetic analyses from adult and pediatric data, which support the proposed dosing regimen in the pediatric population.

Sunovion's ongoing development program for APTIOM includes a Phase 4 study in adults with POS that is designed to evaluate APTIOM in real-world clinical settings supporting the use of APTIOM as adjunctive therapy for POS. The study includes an exploratory endpoint to evaluate the use of the Embrace watch by Empatica, an investigational wearable device with unique proprietary technology, to detect and record POS subjectively identified by patients or caregivers. This is the first time that a wearable seizure detection device has been incorporated into the trial design of an AED for POS such as APTIOM. Additionally, Sunovion is planning a Phase 3 clinical study in children younger than four years of age.

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, immediate release AED FDA-approved for use as monotherapy or adjunctive therapy for partial-onset seizures in adults. 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-Portela & C.[a], 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. 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. 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 and in December 2016, as adjunctive treatment for patients above age six years with partial-onset seizures with or without secondary generalization. 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 2.9 million people are living with active epilepsy, including approximately 460,000 children aged 0 to 17 years.[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 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 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 patients taking APTIOM include dizziness, sleepiness, nausea, headache, double vision, vomiting, feeling tired, problems with coordination, blurred vision, and shakiness.

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.

APTIOM is used under license from Bial.

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 commercialization of important therapies has included Brovana® (arformoterol tartrate), Latuda® (lurasidone HCI) 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, Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, and Sunovion CNS Development Canada ULC, based in Toronto, 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.

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

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