Sunovion to Present Data on Aptiom® (eslicarbazepine acetate) at the American Epilepsy Society (AES) Annual Meeting 2017

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MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion (eslicarbazepine acetate) will present nine posters on APTIOM® (eslicarbazepine acetate) at the American Epilepsy Society (AES) Annual Meeting 2017, taking place December 1-5, 2017, in Washington, D.C.

APTIOM is a once-daily, immediate release antiepileptic drug (AED) that is approved in the U.S. for the treatment of partial-onset seizures (POS) in individuals four years of age and older. Sunovion recently received approval in the U.S. to expand the indication for APTIOM to include treatment of POS in adolescents and children four to 17 years of age.

“Epilepsy is one of the most common neurological conditions in the U.S., affecting approximately 3.4 million people, including an estimated 470,000 children and adolescents,” said David Blum, M.D., Global Head, Neurology Clinical Research at Sunovion. “Sunovion’s presentations of APTIOM data at AES underscore our continued commitment to the epilepsy community and to furthering the understanding of the treatment of partial-onset seizures.”

Sunovion presentations at AES 2017 include:

- Poster #1.280: Adverse Event Incidence According to Baseline Antiepileptic Drug Use: A Pooled Analysis of Data from Phase III Trials of Adjunctive Eslicarbazepine Acetate in Children (Saturday, December 2, 2017, 12:00 – 2:00 p.m. EST, Exhibit Hall)
- Poster #1.288: Design of a Multicenter Study of Eslicarbazepine Acetate as a First Add-On to Initial Levetiracetam or Lamotrigine Monotherapy and as Later Adjunctive Therapy for Uncontrolled Partial-Onset Seizures (Saturday, December 2, 2017, 12:00 – 2:00 p.m. EST, Exhibit Hall)
- Poster #1.294: An Analysis of the Accuracy and Utility of Automated Kit Assays in Quantifying Thyroid Hormone Levels in Patients Taking Eslicarbazepine Acetate (Saturday, December 2, 2017, 12:00 – 2:00 p.m. EST, Exhibit Hall)
- Poster #2.274: Sodium and Thyroid Hormone Levels During Phase III Trials of Adjunctive Eslicarbazepine Acetate, According to Concomitant Antiepileptic Drug Use (Sunday, December 3, 2017, 12:00 – 2:00 p.m. EST, Exhibit Hall)
- Poster #2.275: Analysis of Psychiatric Adverse Events in Two Phase III Conversion to Eslicarbazepine Acetate Monotherapy Trials (Sunday, December 3, 2017, 12:00 – 2:00 p.m. EST, Exhibit Hall)
- Poster #2.276: Analysis of Cognitive Adverse Events in Two Phase III Conversion to Eslicarbazepine Acetate Monotherapy Trials (Sunday, December 3, 2017, 12:00 – 2:00 p.m. EST, Exhibit Hall)
- Poster #2.277: An Analysis of the Efficacy and Tolerability of Eslicarbazepine Acetate (ESL) by Study Period in Two Phase III Conversion-to-ESL Monotherapy Trials (Sunday, December 3, 2017, 12:00 – 2:00 p.m. EST, Exhibit Hall)
- Poster #2.278: Incidence of Hyponatremia and Changes in Sodium Levels in Phase II/III Trials of ESL in Pediatric Patients (aged 4-17 years) (Sunday, December 3, 2017, 12:00 – 2:00 p.m. EST, Exhibit Hall)
- Poster #3.276: Safety and Tolerability of Adjunctive Eslicarbazepine Acetate in Pediatric Patients (aged 4-17 years) with Partial-Onset Focal Seizures (Monday, December 4, 2017, 12:00 – 2:00 p.m. EST, Exhibit Hall)

About Aptiom® (eslicarbazepine acetate)

APTIOM is a member of the dibenzepine 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, adolescents and children (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. 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. Epilepsy manifests as unprovoked seizures, which are caused by abnormal firing of impulses from nerve cells in the brain. 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. 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. Up to 40 percent of people living with epilepsy do not respond to the first or second monotherapy, and approximately 36 percent fail to achieve adequate control of seizures despite the use of two or more antiepileptic medications.

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; or if your red blood cell count is low. APTIOM may cause your birth control medicine to be less effective. 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.

**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 about any of the following medicines: carbamazepine, phenobarbital, phenytoin, primidone, clozapam, 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 affect 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, breast feeding or plan to breast feed. You and your health care provider should 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 [13] or call 1-800-FDA-1088.

For more information, please see the APTIOM Medication Guide [14] and Full Prescribing Information [15].

**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 Utbrona™ Neohaler® (indacaterol/glycopyrrolate) Inhalation Powder, Seebri™ Neohaler® (glycopyrrolate) Inhalation Powder, Brovana® (arformoterol tartrate) Inhalation Solution, Latuda® (lurasidone HCl) and Apliom® (eslicarbazepine acetate).


**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 Pharmaceutical 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 [13].

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For a copy of this release, visit Sunovion's web site at www.sunovion.com [14].

**References**


5. Brodie MJ, Barry SJE, Bamagous GA, Norrie JD, Kwan P. Patterns of Epilepsy Foundation. “If First Medicine Doesn’t Work” 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 Pharmaceutical 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 [13].

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**References**


