Sunovion Pharmaceuticals Inc. to Present Data on Aptiom® (eslicarbazepine acetate) at 67th American Academy of Neurology Annual Meeting

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Phase 3 data evaluate use of APTIOM as a potential monotherapy treatment for partial-onset seizures

MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc. (Sunovion) will present five research posters at the 67th American Academy of Neurology (AAN) Annual Meeting (April 18-23, Washington, D.C.) by outlining findings from two pooled Phase 3 studies (Studies 093-045 and 093-046) evaluating the safety and efficacy of APTIOM® (eslicarbazepine acetate) as a potential monotherapy treatment of partial-onset seizures. Sunovion’s supplemental New Drug Application (sNDA) for the use of APTIOM as a monotherapy for partial-onset seizures is currently under review by the U.S. Food and Drug Administration (FDA).

“Epilepsy is a significant medical illness. It affects approximately two million people in the U.S., and there is a clear unmet medical need for effective treatments,” said Fred Grossman, D.O., FAPA, Head, Global Clinical Development and Medical Affairs at Sunovion. “Data from our monotherapy clinical trials build upon the established efficacy and safety of APTIOM adjunctive treatment and may provide a potential new option for patients with epilepsy who could benefit from monotherapy.”

APTIOM is approved for use as adjunctive treatment of partial-onset seizures. APTIOM was launched in the United States on April 7, 2014. APTIOM is not approved for use as monotherapy for partial-onset seizures.

APTIOM Poster Presentations
Poster Session I - Epilepsy/Neurophysiology (EEG) – Monday, April 20, 2015, 2:00 p.m. – 6:30 p.m. EDT
Poster 1.250 – Eslicarbazepine Acetate (ESL) Monotherapy in Adults with Partial-Onset Seizures (POS): an Analysis of Pooled Data from Two Phase 8 Studies, with Use of a Historical Control
Authors: Ladasib Pazera, Jacqueline French, Michael Sperling, Mercedes Jacobson, Haong Cheng, David Blum

An analysis of two pooled Phase 3 clinical trials evaluating eslicarbazepine acetate as monotherapy showed that exit rates for eslicarbazepine acetate as monotherapy (1,600 mg/day and 1,200 mg/day) were superior to a historical control. The two identically designed Phase 3 trials investigated conversion from adjunctive therapy (1-3 concomitant antiepileptic drugs [AEDs]) to monotherapy with eslicarbazepine acetate. The primary endpoint for both studies was the proportion of patients meeting pre-defined exit criteria (signifying worsening seizure control) compared to a historical control. Treatment was considered effective if the upper limit of the 95% confidence interval (CI) for the exit rate was lower than a pre-specified threshold based on historical controls. The pooled estimated exit rates for eslicarbazepine acetate were 20.6% (95% CI: 15.6-26.8%) for the 1,600 mg/day dose and 30.8% (95% CI: 23.0-40.5%) for the 1,200 mg/day dose, lower than historical thresholds of 65.3% (for a single study) and 72.2% (for two independent studies). Eslicarbazepine acetate was also well-tolerated as monotherapy, with only headache occurring in ≥5% of both dose groups. Data from these trials, including Study 093-045, the first AED trial of its kind conducted in an exclusively North American population, was included in Sunovion’s sNDA submission for APTIOM as monotherapy treatment.

Poster 1.233 – Abuse Potential of Antiepileptic Drugs: a Review Using the VigiBase™ Pharmacovigilance Database
Authors: Barry Gidal, David Blum

Findings from a review of VigiBase®, a searchable World Health Organization (WHO) Global Individual Case Safety Report (ICSR) database, showed that potentially abuse-related adverse events (AEs) were reported more frequently for lacosamide and pregabalin than for eslicarbazepine acetate, oxcarbazepine or carbamazepine. The review identified incidence rates per 100 patient-years for potentially abuse-related AEs including euphoric mood, hallucination, drug dependence, drug abuse and withdrawal. APTIOM is not classified as a controlled substance by the FDA.

Poster 1.234 – Changes in Quality of Life (QoL) and Depressive Symptoms in a Long-term Open-label Extension (OLE) of Eslicarbazepine Acetate (ESL) Monotherapy Studies in Adults with Refractory Partial-Onset Seizures (POS)
Authors: Frank Gilliam, Haong Cheng, David Blum

An analysis of two identically designed Phase III studies (301, 302 and 304) showed that the incidence of falls, fractures and injuries was low (<10%). The overall incidence of falls, fractures and injuries was similar for the eslicarbazepine acetate 400 mg, 800 mg and 1,200 mg/day groups (5.1%, 9.4% and 5.1%) and for the placebo group (6.1%) and the incidence did not increase with eslicarbazepine acetate dose. Falls, contusions and head injuries were reported most frequently (>2%) in this category of treatment-emergent AEs.

Poster 4.258 – Incidence of Falls, Fractures, and Injuries with Eslicarbazepine Acetate in Adult Outpatients with Partial-Onset Seizures: a Pooled Analysis of Three Placebo-Controlled Trials
Authors: William Rosenfeld, Selim Berbais, Pavel Klei, Luigi Maria Specchio, Pedro Kwacs, Helena Gama, Francisco Rocha, Raymond Claus, David Blum

Findings from an analysis of three pooled placebo-controlled studies (Studies 301, 302 and 304) showed that the incidence of falls, fractures and injuries was low (<10%). The overall incidence of falls, fractures and injuries was similar for the eslicarbazepine acetate 400 mg, 800 mg and 1,200 mg/day groups (5.1%, 9.4% and 5.1%) and for the placebo group (6.1%) and the incidence did not increase with eslicarbazepine acetate dose. Falls, contusions and head injuries were reported most frequently (>2%) in this category of treatment-emergent AEs.

About Partial-Onset Seizures
Epilepsy is characterized by abnormal firing of impulses from nerve cells in the brain. 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. The unpredictable nature of seizures can have a significant impact on those with epilepsy, affecting a number of areas in daily living, including employment, driving and insurance. Reducing the frequency of seizures can greatly 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.

About APTIOM® (eslicarbazepine acetate)
APTIOM, a voltage-gated sodium channel inhibitor, is a prescription medicine approved for use as adjunctive treatment of partial-onset seizures, 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.

The initial research and development of eslicarbazepine acetate was gained approval for eslicarbazepine acetate from Sunovion’s sNDA submission for APTIOM as monotherapy for partial-onset seizures. Sunovion’s supplemental New Drug Application (sNDA) for the use of APTIOM as monotherapy for partial-onset seizures is currently under review by the U.S. Food and Drug Administration (FDA).

APTIOM is not approved for use as monotherapy for partial-onset seizures.

APTIOM may cause the level of a sodium-containing substance 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.

Important Safety Information:

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

**Please see Important Safety Information below.**
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: clobazam, carbamazepine, phenobarbital, phenytoin, primidone, coenzyme Q10, 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: Do not start taking APTIOM until you and your healthcare provider talk 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 (at: www.sunovion.com) and Full Prescribing Information (at: www.APTIOM.com).

About Sumovion 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 to improve the lives of patients and their families.


About Sumitomo Dainippon Pharma Co., Ltd.

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

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Sources:

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

References


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