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

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Terms:

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MARLBOROUGH, Mass. -- (BUSINESS WIRE) -- Sunovion Pharmaceuticals Inc. (Sunovion) will present five research posters at the 67th American Academy of Neurology (AAN) Annual Meeting (April 18-22, Washington, D.C.) by analyzing 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 potential 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/Clinical 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 3 Studies, with Use of a Historical Control
Authors: Latibah Pazeera, Jacqueline French, Michael Sperling, Mercedes Jacobson, Hakong 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 control condition. The two studies were designed as a phase 3, 12-month randomized, double-blind, placebo-controlled, parallel-group study in adults (18 to 70 years of age) with POS. The primary endpoint for both studies was the proportion of patients meeting pre-defined exit criteria (signifying worsening seizure control) compared to a control condition. 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 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 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 Gillam, Hakong Cheng, David Blum

Findings from analysis of three pooled Phase 3 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, confusions and head injuries were reported most frequently (≥2%) in this category of treatment-emergent AEs.

Poster 4.277 – Incidence of Falls, Fractures, and Injuries with Adjunctive Eslicarbazepine Acetate (ESL) in Patients with Partial-Onset Seizures (POS): A Pooled Analysis of Three Placebo-Controlled Trials
Authors: William Rosenberg, Selin Benbadi, Pavel Kleis, Luigi Maria Sperchio, Pedro Kovacs, Helena Gama, Francisco Rocha, Raymond Claus, David Blum

Findings from an analysis of three pooled Phase 3 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, confusions, 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. 1 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 area. 2 The unpredictable nature of seizures can have a significant impact on those with epilepsy, affecting a number of areas including daily living, employment, driving and exercise. Reducing the frequency of seizures can greatly lessen the burden of epilepsy. 3 With approximately one-third of people living with epilepsy still unable to control seizures, there continues to be a need for new therapies. 5

About APTIOM® (eslicarbazepine acetate)

APTIOM® is a voltage-gated sodium channel inhibitor that 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 and subsequent development of eslicarbazepine acetate was performed by Bial-Portela & Ca, 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 Canadian markets from BIAL. BIAL gained approval for eslicarbazepine acetate in the European Commission on April 21, 2009 as adjunctive therapy in adult patients with partial-onset seizures with or without secondary generalization.

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 severe 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; fever; swollen glands, or sore throat that do not go away or come and go; painful sores in the mouth or on your lips; 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

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