Sunovion Pharmaceuticals Inc. Presents Data on Aptiom® (eslicarbazepine acetate) at 66th American Academy of Neurology Annual Meeting

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Results Underscore Importance of New Adjunctive Treatment Option for Partial-Onset Seizures

MARLBOROUGH, Mass. – (BUSINESS WIRE) -- Sunovion Pharmaceuticals Inc. (Sunovion) is presenting new findings from sub-analyses of the pooled Phase 3 studies (Studies 301, 302 and 304) evaluating the safety and efficacy of APTIOM® (eslicarbazepine acetate) as adjunctive treatment of partial-onset seizures. These presentations at the 66th American Academy of Neurology (AAN) Annual Meeting (April 26 - May 3, Philadelphia) continue to demonstrate the importance of new treatment options for partial-onset seizures, such as APTIOM.

*APTIOM has been well-received by healthcare professionals since its recent market introduction in the United States. The APTIOM data presented at AAN support the efficacy and safety profile that led to its FDA approval for use as adjunctive treatment for partial-onset seizures.* said Fred Grossman, D.O., FAPA, Senior Vice President, Clinical Development and Medical Affairs at Sunovion. APTIOM, a voltage-gated sodium channel blocker, is now available by prescription in pharmacies across the United States. Recognized as a new molecular entity by the U.S. Food and Drug Administration (FDA), APTIOM was approved on November 8, 2013, for use as adjunctive treatment of partial-onset seizures.¹

Thirteen Sunovion-supported analyses will be presented at this year’s AAN Annual Meeting, including eight regarding APTIOM and five presentations of new healthcare economics and outcomes research in epilepsy.

APTIOM® Poster Presentations

Poster Session B – Epilepsy and Clinical Neurophysiology: A4D – Tuesday, April 29, 2014 from 3:00 p.m. EDT until 6:30 p.m. EDT

Poster 2.239 – Efficacy of Eslicarbazepine Acetate in Patients with Refractory Partial-Onset Seizures Treated With or Without Concomitant Carbamazepine: A Pooled Analysis of Three Phase B Controlled Studies

The efficacy analysis of the pooled Phase 3 APTIOM studies demonstrated that both APTIOM 800 mg and 1,200 mg once-daily for the adjunctive treatment of partial-onset seizures were efficacious in reducing standardized seizure frequency (SSF) among treatment-resistant epilepsy patients with partial-onset seizures, with or without concomitant carbamazepine use (CBZ: 7.5 vs. 5.7 (p=0.012), 4.9 (p<0.0001); +CBZ: 8.0 vs. 6.5 (p=0.005), 6.6 (p=0.001)). The data suggest that the efficacy of APTIOM is similar with and without the concomitant use of carbamazepine, an antiepileptic drug with a proposed mechanism of action similar to that of APTIOM.

Poster 2.237 – Safety of Eslicarbazepine Acetate in Patients with Refractory Partial-Onset Seizures Treated With or Without Concomitant Carbamazepine: A Pooled Analysis of Three Phase B Controlled Studies

Findings from the pooled APTIOM Phase 3 studies’ safety analysis in patients treated with or without carbamazepine suggest that some adverse events were more frequent in patients using concomitant carbamazepine. Results demonstrated dizziness (800 mg: 15.9% vs. 4.9%; 1,200 mg: 26.2% vs. 11.5%), diplopia (800 mg: 11.7% vs. 2.9%; 1,200 mg: 13.2% vs. 4.5%), vomiting (800 mg: 6.3% vs. 6.6%; 1,200 mg: 9.7% vs. 5.1%) and nausea (800 mg: 5.2% vs. 3.7%; 1,200 mg: 13.0% vs. 7.7%) were more frequent, and somnolence (1,200 mg: 4.1% vs. 14.8%) and tremor (1,200 mg: 0% vs. 6.9%) were less frequent.

Additional APTIOM data presentations include:

- Poster 3.238 – Effects of Eslicarbazepine Acetate on Cardiac Function in Patients with Refractory Partial-Onset Seizures: A Pooled Analysis of Three Phase B Controlled Studies
- Poster 3.460 – Safety of Eslicarbazepine Acetate in Elderly Subjects: A Pooled Analysis of Five Phase B Placebo-Controlled Non-Epilepsy Studies
- Poster 3.241 – Incidence of Allergic Reaction Adverse Events during Adjunctive Treatment with Eslicarbazepine Acetate in Patients with Refractory Partial-Onset Seizures: A Pooled Analysis of Three Phase B Placebo-Controlled Studies
- Poster 3.242 – Conversion to Monotherapy with Eslicarbazepine Acetate in Adults with Partial-Onset Seizures: Results of a North American Study (Note: Monotherapy use of APTIOM is not approved by FDA or EMA)
- Poster 3.243 – Co-administration of Carbamazepine with Eslicarbazepine Acetate Decreases Eslicarbazepine Exposure: A Population Pharmacokinetic Analysis
- Poster Session VI – Epilepsy and Clinical Neurophysiology (EEG): Quality of Life and Comorbidities – Thursday, May 1, 2014 from 7:30 a.m. EDT until 11:00 a.m. EDT
- Poster 3.168 – Impact of Seizure Frequency Reduction on Health-Related Quality of Life Among Clinical Trial Subjects with Refractory Partial-Onset Seizures: A Pooled Analysis of Phase III Clinical Trials of Eslicarbazepine Acetate

About APTIOM Phase 3 Studies 301, 302 and 304

Studies 301, 302 and 304 were Phase 3 randomized, double-blind, placebo-controlled safety and efficacy trials of similar study design, involving more than 1,400 patients with partial-onset seizures inadequately controlled by one to three concomitant antiepileptic drugs (AEDs) (including carbamazepine, lamotrigine, valproic acid and levetiracetam) to evaluate the safety and efficacy of APTIOM for the adjunctive treatment of partial-onset seizures. The primary endpoint for all three studies was the standardized seizure frequency per four weeks during the maintenance phase. Secondary endpoints included relative change in seizure frequency from baseline and responder rates (percent of patients with a 50 percent or 75 percent seizure reduction). Results demonstrated the safety and efficacy of APTIOM as an adjunctive therapy of partial-onset seizures. The FDA approval of APTIOM was supported by the findings of these pivotal studies.

About Partial-Onset Seizures

Epilepsy is one of the most common neurological disorders and affects nearly 2.2 million people in the United States.² Epilepsy is characterized by abnormal firing of impulses from nerve cells in the brain.³ Partial-onset seizures are the most prevalent seizure type, accounting for approximately 60 percent of all epilepsy diagnoses.⁴ In partial-onset seizures, 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.⁵ The unpredictable nature of seizures can greatly lessen the quality of life and can greatly lessen the burden of epilepsy.²

About APTIOM

APTIOM, a voltage-gated sodium channel blocker, is a prescription medicine approved for use as adjunctive treatment of partial-onset seizures. APTIOM is available in four tablet strengths (200 mg, 400 mg, 600 mg and 800 mg), which can be taken whole or crushed, or with or without food.

The safety and efficacy of APTIOM was established in three Phase 3 randomized, double-blind, placebo-controlled trials of more than 1,400 people living with partial-onset seizures inadequately controlled by one to three concomitant AEDs (including carbamazepine, lamotrigine, valproic acid and levetiracetam). These studies showed that treatment with APTIOM demonstrated statistically significant reductions in standardized seizure frequency versus placebo, and more APTIOM treated patients experienced seizure frequency reduction of 50 percent or more from baseline (41% compared to 22% for placebo-treated patients). The most common side effects in patients taking APTIOM included dizziness, sleepiness, nausea, headache, double vision, vomiting, feeling tired, problems with coordination, blurred vision and rashiness.

Sunovion acquired the rights under an exclusive license to further develop and commercialize eslicarbazepine acetate in the United States and Canadian markets from BIAL-Portela & Cia, S.A. (BIAL), a privately held Portuguese research-based pharmaceutical company. BIAL conducted the initial research and development of eslicarbazepine acetate and, in April 2009, received approval from the European Commission for the use of eslicarbazepine acetate as adjunctive therapy in adult patients with partial-onset seizures with or without secondary generalization. In Europe, the product is marketed under the trade name Zebrin®.

Please see Important Safety Information below.

Indication:

Aptiom® (eslicarbazepine acetate) is a prescription medicine used with other medicines to treat partial-onset seizures.

重大安全性信息:

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
rasp with these reactions of rash. 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 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, feeling tired, problems with coordination, blurred vision, and slackness.

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 taking APTIOM with other antiepileptic medicines if you take oxcarbazepine, carbamazepine, phenobarbital, phenytoin, primidone, clonazepam, lemeflazine, tiagabine, or topiramate, or with sodium valproate, or with bupropion, or with lithium, or with clozapine, or with with alprazolam, or with cilansetron, or with clonazepam, or with diazepam, or with rofecoxib, or with naproxen, or with aspirin, or with fluoxetine, or with trimipramine, or with nortriptyline, or with clonazepam, or with lorazepam, or with midazolam, or with ampicillin, or with cefazolin, or with gentamicin, or with theophylline, or with aminoglycosides, or with warfarin, or with diltiazem, or with ciprofloxacin, or with dexamethasone, or with lithium, or with indomethacin, or with quinapril, or with aspirin, or with nortriptyline, or with lithium, or with theophylline.

Discontinuation: Do not stop taking APTIOM without talking to your healthcare 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 healthcare provider about the best birth control method to use. APTIOM may harm your baby. APTIOM passes into breast milk. Tell your healthcare provider if you are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. You and your healthcare provider will decide if you should stop taking APTIOM. If you become pregnant while taking APTIOM, talk to your healthcare 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 at www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information, please see the APTIOM Medication Guide [2] and Full Prescribing Information [3].

About Sunovion 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. Sunovion's drug development program, together with its corporate development and licensing efforts, has yielded a portfolio of pharmaceutical products including Aptiom® (eslicarbazepine acetate), Latuda® (laruxoline HCl tablets), Lenvita® (eslicarbazepine AIC Tablets), Xopenex® (levalbuterol HCl inhalation solution), Xopenex HFA® (levalbuterol tartrate) inhalation aerosol, Brovana® (arformoterol tartrate) inhalation solution, Omnar® (ciclesonide) nasal spray, Zetrona® (ciclesonide) nasal aerosol and Avelco® (ciclesonide) inhalation aerosol.


About Dainippon Sumitomo Pharma Co., Ltd. (DSP)

DSP is a top-ten listed pharmaceutical company in Japan with a diverse portfolio of pharmaceutical, animal health and food and specialty products. DSP aims to produce innovative pharmaceutical products with new mechanisms of action and novel therapeutic strategies to address unmet medical needs in the Psychiatry & Neurology and the Oncology area, which have been designated as the Focus therapeutic areas. DSP is based on the merger in 2005 between Dai sprzedaży Pharmaceutical Co., Ltd. and Sumitomo Pharmaceuticals Co., Ltd. Today, DSP has about 7,000 employees worldwide. Additional information about DSP is available through its corporate website at www.dsp-pharma.com.

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