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News Release

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NEW STEDESA™ CLINICAL DATA PRESENTED AT AMERICAN EPILEPSY SOCIETY ANNUAL MEETING

Among the new data presented were an investigation of cerebrospinal fluid and plasma pharmacokinetics, metabolic parameters and utilization with and without levetiracetam

MARLBOROUGH, Mass., December 4, 2010 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that clinical study data for STEDESA™ (eslicarbazepine acetate [ESL]) were presented during a scientific poster session at the 2010 annual meeting of the American Epilepsy Society (AES) in San Antonio, Texas. Three posters were presented during the scientific poster sessions. The first was based on data from a Phase I study of cerebrospinal fluid (CSF) and plasma pharmacokinetics of ESL and oxcarbazepine (OXC). Two other posters included safety and efficacy derived from the pooled results of two, placebo-controlled Phase III studies of ESL in which patients had a history of at least four partial-onset seizures per month despite treatment with one to three concomitant antiepileptic drugs (AEDs) and who were randomized to ESL 400 mg, 800 mg, 1200 mg or placebo.

Cerebrospinal Fluid and Plasma Pharmacokinetics of Eslicarbazepine Acetate and Oxcarbazepine in Healthy Volunteers

ESL and OXC are orally administered and their active metabolites (S-licarbazepine [eslicarbazepine] and R-licarbazepine), as well as a small amount of residual OXC are formed in the periphery and cross the blood-brain barrier to reach their site of action at voltage-gated sodium channels. It is unknown how CSF concentrations of these metabolites correlate with plasma concentrations. To assess this correlation, levels of ESL and OXC, as well as their metabolites were evaluated in the CSF and plasma

Subjects were randomized to either ESL or OXC, titrated over 3 days to 1200 mg ESL once-daily or 600 mg OXC twice-daily, and treated from day 4 to 9. Plasma and CSF samples were collected on Day 1 and 9 (pre-dose and for the duration of the dosing interval (24 hrs for ESL and 12 hrs for OXC) for determination of eslicarbazepine, R-licarbazepine and OXC levels. Pharmacokinetic analyses were performed.

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Fourteen subjects were randomized (7 ESL; 7 OXC) and treated. In the ESL group, the relative plasma exposure to eslicarbazepine, R-licarbazepine, and OXC was 93.84%, 5.20% and 0.96%; and 91.96%, 7.13%, and 0.91% in CSF, respectively. In the OXC group, the relative plasma exposure to eslicarbazepine, R-licarbazepine, and OXC was 78.06%, 18.47%, and 3.47%; and 76.42%, 21.36%, and 2.22% in CSF, respectively. In the ESL group, the apparent half-life of eslicarbazepine was approximately 16 hrs in plasma and approximately 24 hrs in CSF.

In comparison to OXC, administration of ESL resulted in more eslicarbazepine, less R-licarbazepine, and less OXC in plasma and CSF.

An Evaluation of the Effect of Eslicarbazepine Acetate on Weight, Glucose, and Lipids: An Integrated Analysis of Two Double-Blind Phase III Clinical Studies

Studies have suggested that prolonged treatment with AEDs may have some undesirable metabolic effects, including increases in total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), and serum triglycerides (TRIG).[1-7] To gain an understanding of the potential for changes in weight, glucose, alanine transaminase (ALT), aspartate transaminase (AST) , and lipid fractions (TC; LDL-C; HDL-C; TRIG) when using ESL as adjunctive therapy to 1-3 concomitant AEDs, these metabolic parameters were analyzed using pooled data from two Phase III studies in subjects taking ESL compared with placebo.

All subjects (N=797) who received at least one dose of study medication (400 mg, 800 mg, or 1200 mg of ESL or placebo) were included in the analysis. Complete analysis of these data was performed including changes from baseline to the end of the double-blind period (14 weeks) and determination of the proportion of subjects with potentially clinically significant (PCS) findings. PCS values were defined as an increase or decrease of ≥7% in weight; ≤40 mg/dL or ≥175 mg/dL for glucose; ≥3x upper limit of normal (ULN) for AST and ALT; and >300 mg/dL for TC; >160 mg/dL for LDL-C; <30 mg/dL for HDL-C; >2.5 x ULN for TRIG. Treatment emergent adverse events (TEAEs) were defined as an event that occurred on or after the date of first dose, or the date of randomization if the date of the first dose was missing. Mean changes from baseline to the end of the double-blind period (14 weeks) in the metabolic parameters were small in the placebo and ESL groups. The incidence of PCS events related to glucose, AST, and ALT were similar across groups. Small differences in PCS abnormal lipid parameters and weight increase of ≥7% from baseline were observed between the ESL dose groups and the placebo group. There were no glucose abnormalities reported as TEAEs in any group. Weight increase or decrease reported as a TEAE was more prevalent in the ESL 400 mg group compared to the placebo and the 800 mg and 1200 mg ESL groups. TEAEs related to AST and ALT were reported in <1% of subjects receiving ESL. Lipid abnormalities were reported in ≤1% of subjects receiving ESL.

An Exploratory, Subgroup Analysis of the Safety and Efficacy of Eslicarbazepine Acetate Administered Once Daily as Concomitant Treatment to Levetiracetam: An Integrated Analysis of Two Phase III Studies

Levetiracetam (LEV) was identified as a commonly used concomitant antiepileptic drug in two Phase III studies. To gain an understanding of the efficacy, as well as the nature and risk of TEAEs associated with the use of ESL in combination with LEV, a sub-analysis by baseline LEV use was conducted.

Of the 790 subjects included in the efficacy analysis, 96 (12.1%) used AEDs including LEV. The least square mean difference from placebo in standardized seizure frequency in subjects using AEDs including LEV was 2.9, 3.2, and 2.7 compared to 0.6, 2.0, and 2.2 in those subjects using AEDs other than LEV for ESL 400, 800, and 1200 mg, respectively. The power of this analysis was limited by the small number of subjects using LEV vs. those subjects not using LEV. In the safety analysis of 797 subjects, 98 (12.3%) used AEDs including LEV. The incidence of the most common TEAEs was similar between the groups.

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Additional posters for ESL will be presented as part of a Scientific Exhibit on Sunday, December 5, 2010, which will be held from 8:00 am to 5:00 pm EST at the Henry B. Gonzalez Convention Center, Room 103-B.

The studies on which these analyses and posters are based were conducted by BIAL-Portela & C[a], S.A. (BIAL) with additional analysis and editorial support for the posters provided by Sunovion.

About partial-onset seizures and their treatment
Epilepsy is one of the most common neurological disorders that, according to the Epilepsy Foundation, affects more than 3 million people in the United States. Treatment of partial-onset seizures, the most common type of epilepsy, presents a constant challenge – up to 58% of patients with partial-onset seizures do not achieve seizure control with current antiepileptic drugs.[8] Patient compliance with antiepileptic agents represents a significant area of unmet need, with poorly compliant patients more likely to have breakthrough seizures[9] and have higher mortality risk.[10] Additionally, patients with epilepsy often suffer from other concomitant diseases, further complicating the management of these patients.[11] Finally, certain adverse events are highly prevalent with existing antiepileptic agents and may affect as many as 97% of patients.[12]

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. Nerve impulses are triggered in part via voltage-gated sodium channels in the nerve cell membrane.

About STEDESA
The new drug application (NDA) for STEDESA (eslicarbazepine acetate [ESL]) was submitted to the U.S. Food and Drug Administration (FDA) as an adjunctive treatment of partial-onset seizures in adult patients with epilepsy. STEDESA, a new chemical entity, is a novel voltage-gated sodium channel blocker. The STEDESA NDA was based on two Phase III multi-center, randomized, placebo-controlled trials, which involved 797 patients and 22 countries. Patients involved in the trials had a history of at least four partial-onset seizures per month despite treatment with one to three concomitant AEDs. During the trials, patients were randomized to ESL or placebo, and after a 2-week titration period, were assessed over a 12-week maintenance period with continued follow-up over a one-year, open-label period. BIAL-Portela & C[a], S.A. (BIAL), a privately held Portuguese research based pharmaceutical company, was responsible for the research and development of eslicarbazepine acetate. Sunovion Pharmaceuticals Inc., formerly known as Sepracor Inc., acquired the rights to further develop and to commercialize ESL in the U.S. and Canadian markets from BIAL in late 2007. Sunovion is seeking approval of STEDESA for adjunctive therapy for partial-onset seizures in adults with epilepsy with once-daily doses of 800 mg and 1200 mg.

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 central nervous system (CNS) and respiratory disease areas and improve the lives of patients and their families. Sunovion's drug development program, together with its corporate development and licensing efforts, has yielded a portfolio of pharmaceutical products including LATUDA® brand lurasidone HCl, LUNESTA® brand eszopiclone, XOPENEX® brand levalbuterol HCl Inhalation Solution, XOPENEX HFA® brand levalbuterol tartrate inhalation aerosol, BROVANA® brand aformoterol tartrate inhalation solution, OMNARIS® brand ciclesonide nasal spray and ALVESCO® brand ciclesonide HFA inhalation aerosol.

Sunovion, an indirect, wholly-owned subsidiary of Dainippon Sumitomo Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at www.sunovion.com

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