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News Release

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NEW STEDESA™ CLINICAL DATA PRESENTED AT AMERICAN ACADEMY OF NEUROLOGY ANNUAL MEETING

- Sunovion continues strong commitment to the clinical development and U.S. approval of STEDESA™
- Sunovion continues to recruit investigators and clinical trial sites for ongoing epilepsy trials

MARLBOROUGH, Mass., April 11, 2011 – Sunovion Pharmaceuticals Inc. (Sunovion) announced today that they will be recruiting investigators for their ongoing STEDESA™ (eslicarbazepine acetate [ESL]) clinical studies, as well as presenting clinical study data during the scientific poster sessions at the 2011 annual meeting of the American Academy of Neurology (AAN) in Honolulu, Hawaii. STEDESA™ is the company's proposed trade name for eslicarbazepine acetate.

Recruiting Investigators for Ongoing Clinical Studies

As part of Sunovion's booth activities at this years AAN meeting, Sunovion will be recruiting investigators for their ongoing Phase III, double-blind, randomized, placebo-controlled, parallel-group, multicenter clinical study to evaluate the efficacy and safety of once-daily (QD) ESL as adjunctive treatment in adult subjects (≥16 years) with refractory partial-onset seizures. For more information about how to become an investigator for this study, please visit the Sunovion booth (#556) at the Hawaii Convention Center during the scheduled exhibit hall hours or contact Sunovion at epilepsytrials@sunovion.com.

In addition to the ongoing adult adjunct study, Sunovion is also conducting two double-blind, randomized, multicenter, 18-week, historical control studies evaluating the safety and efficacy of ESL monotherapy in adult subjects (≥16 years) with partial-onset seizures not well-controlled by their current antiepileptic drugs (AEDs). In these studies, subjects are being gradually converted from their previous antiepileptic therapy to ESL monotherapy.

As noted by Antony Loebel, M.D., executive vice president, Clinical Research and Medical Affairs at Sunovion Pharmaceuticals Inc., "Sunovion maintains its strong commitment to the clinical development and U.S. approval of eslicarbazepine acetate. Ongoing discussions continue between Sunovion and the U.S. Food and Drug Administration regarding plans to resubmit the New Drug Application."

As part of the AAN meeting, Sunovion will be presenting new clinical data on ESL during the scientific poster sessions on April 13, 2011.

Drug-Drug Interaction (DDI) of Once-daily Eslicarbazepine Acetate with Antiepileptic Drugs

New AEDs are typically initially approved as adjunctive treatment with other AEDs and, consequently, their propensity to interact with the other AEDs is of particular clinical interest.[1] These interactions are either evaluated through studies designed to investigate particular interactions or are based on population data derived from Phase III clinical trials of the drug.[1]

DDIs were evaluated in three separate Phase 1 studies in 32 healthy subjects each (16 per group) where subjects were coadministered ESL 1200 mg QD with lamotrigine, topiramate, or phenytoin. In addition, DDIs of coadministered ESL 1200 mg QD with carbamazepine, phenobarbital, levetiracetam, gabapentin, or valproate were evaluated by performing population pharmacokinetic analyses on data obtained from approximately 800 subjects (100 per treatment group) enrolled in two Phase 3, placebo-controlled, adjunct studies of ESL (400 mg, 800 mg, or 1200 mg QD) for partial-onset seizures.

In these studies, no clinically relevant DDIs were observed when ESL was coadministered with levetiracetam, gabapentin, lamotrigine, topiramate, or valproate. Among antiepileptic drugs only phenytoin, phenobarbital, and carbamazepine showed a clinically meaningful drug-drug interaction with eslicarbazepine acetate.

Coadministration of ESL had an effect on the exposure of the other AED's. In the Phase 1 studies ESL decreased the exposure of lamotrigine (14%) and topiramate (18%), and increased the exposure of phenytoin (35%). In the population pharmacokinetic analysis, coadministration of ESL resulted in a decrease in exposure of levetiracetam (14%) and carbamazepine (4-11%).

In the Phase 1 studies, coadministration of lamotrigine, topiramate and phenytoin decreased the exposure of ESL by 4%, 7%, and 33%, respectively. In the population pharmacokinetic analysis, the exposure of ESL was decreased with carbamazepine (10-25%) and phenobarbital (23%) and increased with valproate (7-24%). Therefore the dose of ESL should be guided by both pharmacokinetic and clinical response. Alterations in exposure to phenytoin suggest that monitoring of phenytoin plasma concentrations may be warranted.

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).[2-8]

To evaluate the effect that ESL had on weight, glucose, lipid fractions, alanine transaminase (ALT), and aspartate transaminase (AST) an analysis was conducted in subjects (N=797) who participated in two Phase 3, multi-center, randomized, placebo-controlled studies of ESL (400 mg, 800 mg, or 1200 mg QD) as adjunct therapy for partial-onset seizures.

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 potentially clinically significant (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 was no glucose abnormalities reported as treatment related adverse events (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.

In addition to these data being presented at AAN, Sunovion will also be presenting three other scientific posters, which include data from a Phase I study of cerebrospinal fluid and plasma pharmacokinetics of ESL and oxcarbazepine, as well data from a population based pharmacokinetic/pharmacodynamic exposure-response model.

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 adequate seizure control with current antiepileptic drugs.[9] Patient compliance with antiepileptic agents represents a significant area of unmet need, with poorly compliant patients more likely to have breakthrough seizures[10] and have higher mortality risk.[11] Additionally, patients with epilepsy often suffer from other concomitant diseases, further complicating the management of these patients.[12] Finally, certain adverse events are highly prevalent with existing antiepileptic agents and may affect as many as 97% of patients.[13]

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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