

Sunovion Pharmaceuticals Inc.

84 Waterford Drive, Marlborough, MA 01752-7010

Tel 508-481-6700

## News Release

**Contact:** Susan Alesina  
Vice President, Corporate Communications  
Sunovion Pharmaceuticals Inc.  
508-481-6700  
susan.alesina@sunovion.com

---

### **STEDESAS<sup>TM</sup> CLINICAL DATA PRESENTED AT 2011 AMERICAN EPILEPSY SOCIETY ANNUAL MEETING**

- Sunovion reaffirms commitment to once-daily epilepsy compound STEDESAS
- Development path targets STEDESAS (eslicarbazepine acetate) NDA resubmission during the third quarter of 2012

MARLBOROUGH, Mass., December 2, 2011 – Sunovion Pharmaceuticals Inc. (Sunovion) announced today that the company has finalized its plans for resubmitting the New Drug Application (NDA) for STEDESAS<sup>TM</sup> (eslicarbazepine acetate [ESL]) to the U.S. Food and Drug Administration (FDA). Sunovion received a Complete Response Letter from the FDA in April 2010, and since then has identified a path forward for the NDA resubmission. Results of an ongoing clinical trial are expected to be available in the second quarter of 2012, and will be included in the STEDESAS NDA resubmission.

“Sunovion is pleased to reaffirm our strong commitment to the development of eslicarbazepine acetate for the treatment of adult partial-onset epilepsy and we look forward to the resubmission of the NDA during the third quarter of 2012,” said Antony Loebel, M.D., Chief Medical Officer at Sunovion Pharmaceuticals Inc. “We believe that eslicarbazepine acetate has significant potential to address current unmet needs in the treatment of patients with epilepsy.”

### **Eslicarbazepine Acetate Data Presented at the 2011 American Epilepsy Society Annual Meeting**

Poster presentations will report integrated data from two Phase III, randomized, double-blind, placebo-controlled, multicenter trials including adult patients (18-75 years of age) with partial-onset seizures with or without secondary generalization not adequately controlled with one to three antiepileptic drugs (AEDs). Patients were required to have at least four partial seizures in each 4-week period during the 8-week baseline period prior to randomization with no seizure-free interval exceeding 21 consecutive days. In these two trials, patients had a mean duration of epilepsy of 22 years and a median baseline seizure frequency ranging from 15 to 17 per 4-week interval. Sixty-six percent (66%) of patients were taking 2 or more concomitant AEDs. The poster presentations are based on the integrated analysis of 797 patients who received at least 1 dose of study medication (ESL 400 mg QD [n=196], 800 mg QD [n=199], 1200

mg QD [n=200]) or placebo [n=202]. In these studies, the most commonly used concomitant AEDs were carbamazepine ([CBZ]; 58.7%), lamotrigine (23.5%), valproic acid (23.5%), and topiramate (16.7%).

Highlights from four separate poster presentations are listed below:

- **Efficacy of eslicarbazepine acetate by type of concomitantly used AEDs: an exploratory integrated analysis of two Phase III studies (Poster #2.253)**

In these studies, adjunct treatment with ESL 800 and 1200 mg QD had a consistent effect in reducing seizure frequency compared to placebo independent of type of concomitant-AEDs.

- **Safety of eslicarbazepine acetate by type of concomitantly used AEDs: an exploratory integrated analysis of two Phase III studies (Poster #2.254)**

ESL was well tolerated as adjunctive treatment in these studies. In this analysis, the tolerability of ESL was different in patients who were using CBZ concomitantly. In combination with CBZ, TEAEs occurring in  $\geq 10\%$  of subjects were dizziness (29%), headache (15%), diplopia (14%), and somnolence (12%). In subjects who did not have CBZ as one of their concomitant AEDs, the incidence was lower for: dizziness (10%), headache (8%), and diplopia (2%); the only TEAE occurring in  $>10\%$  of these subjects was somnolence (15%). The limitation of this analysis was that most of the patients in both CBZ and non-CBZ groups were on more than a single concomitant AED and the impact of these combinations could not be assessed.

- **The incidence of cognitive adverse events related to eslicarbazepine acetate: an integrated analysis (Poster #2.256)**

The incidence of TEAEs that were identified as related to cognitive dysfunction was  $\leq 2\%$  in all ESL dose group, with the highest incidence observed in the ESL 1200 mg group.

- **An investigation of the incidence and time to onset of adverse events associated with eslicarbazepine acetate adjunct treatment: an integrated analysis of two double-blind placebo-controlled trials (Poster #2.257)**

In this analysis, TEAEs were most likely to begin during the initiation of therapy, with approximately 30% occurring during the first week of treatment in the ESL and placebo groups and the incidence declined in later weeks. There appeared to be a dose related relationship in frequency of TEAEs during the initial 4-weeks of treatment, but time of onset of TEAEs was similar across treatment groups. After 4 weeks of treatment the incidence of new TEAEs appeared similar in the active and placebo treatment groups.

The studies from which these analyses and posters are based were conducted by BIAL-Portela & C<sup>a</sup>, S.A. (BIAL) with additional analysis and editorial support provided by Sunovion.

### **About partial-onset seizures and their treatment**

Epilepsy is one of the most common neurological disorders and, 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 AEDs.<sup>1</sup> Patient compliance with

antiepileptic agents represents a significant area of unmet need, with poorly compliant patients more likely to have breakthrough seizures<sup>2</sup> and higher mortality risk.<sup>3</sup> Furthermore, adverse events are common with existing antiepileptic agents and create a burden for patients. Additionally, patients with epilepsy often suffer from other concomitant diseases, further complicating the management of these patients.<sup>4</sup>

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**

Sunovion is seeking approval of once-daily doses of STEDESA™ (eslicarbazepine acetate) 800 mg and 1200 mg as an adjunctive treatment of partial-onset seizures in adult patients with epilepsy. The NDA for STEDESA as an adjunctive treatment of partial-onset seizures in adult patients with epilepsy was submitted to the FDA in March 2009. Sunovion is also actively conducting clinical trials to evaluate the efficacy of STEDESA monotherapy 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<sup>a</sup>, S.A. (BIAL), a privately held Portuguese research based pharmaceutical company, was responsible for the research and development of ESL. In late 2007, Sunovion Pharmaceuticals Inc., formerly known as Sepracor Inc., acquired the rights to further develop and commercialize ESL in the U.S. and Canadian markets from BIAL.

STEDESA™ is Sunovion's proposed trade name for eslicarbazepine acetate.

### **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 formoterol 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](http://www.sunovion.com).

References:

- <sup>1</sup> Brodie MJ. Management strategies for refractory localization-related seizures. *Epilepsia* 2001;42(Suppl 3):27-30.
- <sup>2</sup> Cramer JA, Glassman M, Rienzi V. The relationship between poor medication compliance and seizures. *Epilepsy Behav.* 2002;3:338-342.
- <sup>3</sup> Faught E, Duh, M, Weiner J, Guerin A, Cunnington M. Nonadherence to antiepileptic drugs and increased mortality, Findings from the RANSOM Study. *Neurology* 2008; 71: 1572-1578.
- <sup>4</sup> Gidal BE, French JA, Grossman P, Le Teuff G. Assessment of potential drug interactions in patients with epilepsy: Impact of age and sex. *Neurology* 2009; 72: 419-431.

LATUDA is a registered trademark of Daiippon Sumitomo Pharma Co., Ltd. LUNESTA, XOPENEX, XOPENEX HFA and BROVANA are registered trademarks of Sunovion Pharmaceuticals Inc. STEDESA is a trademark of BIAL-Portela & C<sup>a</sup>, S.A. OMNARIS and ALVESCO are registered trademarks of Nycomed GmbH.

For a copy of this release or any recent release,  
visit Sunovion's web site at [www.sunovion.com](http://www.sunovion.com).

###