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News Release

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Sunovion Announces FDA Acceptance for Review of New Drug Application Resubmission for STEDESA[®] (eslicarbazepine acetate) as a Once-Daily Adjunctive Therapy for Partial-onset Seizures in Adults with Epilepsy

Marlborough, Mass, February 27, 2013 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's New Drug Application (NDA) resubmission for STEDESA[®] (eslicarbazepine acetate) for use as a once-daily adjunctive therapy in the treatment of partial-onset seizures in patients 18 years and older with epilepsy. STEDESA[®] is the proposed trade name for eslicarbazepine acetate.

"We are pleased to achieve this regulatory milestone for STEDESA[®], which, if approved, may offer adult patients living with epilepsy an effective, once-daily, adjunctive treatment option for managing partial-onset seizures," said Fred Grossman, D.O., FAPA, Senior Vice President, Clinical Development and Medical Affairs at Sunovion. "Adequate seizure control of this most common form of epilepsy remains an unmet medical need for a significant number of patients and Sunovion is committed to providing a treatment option to help address this need."

The NDA for STEDESA[®] is supported by data from three Phase III randomized, double-blind, placebo-controlled 12-week maintenance trials of similar study design, which included more than 1,300 patients with partial-onset seizures in 35 countries, including the United States. Treatment with STEDESA[®] demonstrated statistically significant reductions in standardized seizure frequency when used as adjunctive therapy. The most commonly reported adverse events in the clinical trials were dizziness, somnolence, headache, nausea, diplopia, vomiting, fatigue, ataxia, vision blurred, and vertigo.

The original NDA was submitted to the FDA in March 2009. This resubmission was prepared by Sunovion following receipt of the FDA's April 2010 Complete Response Letter and subsequent correspondence requesting additional information. Eslicarbazepine acetate is currently marketed in Europe by BIAL-Portela & C^a, S.A and by BIAL's licensee, Eisai Europe Limited, a UK subsidiary of Eisai Co., Ltd. under the trade name Zebinix[®]. Zebinix[®] was approved by the European Commission on April 21, 2009 as adjunctive therapy in adult patients with partial-onset seizures with or without secondary generalization.

Sunovion and BIAL are also conducting clinical trials to evaluate eslicarbazepine acetate as monotherapy in the treatment of partial-onset seizures in adult patients with epilepsy.

About Partial-onset Seizures

Epilepsy is one of the most common neurological disorders and, according to the Centers for Disease Control and Prevention, affects nearly 2.2 million people in the United States.ⁱ It is characterized by abnormal firing of impulses from nerve cells in the brain.ⁱⁱ 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.^{iii,iv}

About STEDESA[®]

STEDESA[®] (eslicarbazepine acetate) is an investigational voltage-gated sodium and T-type calcium channel blocker that has been evaluated in three Phase III clinical trials involving more than 1,300 patients with partial-onset epilepsy worldwide. BIAL-Portela & C^a, S.A., a privately held Portuguese research based pharmaceutical company, was responsible for the initial research and development of eslicarbazepine acetate. In late 2007, Sunovion Pharmaceuticals Inc., formerly known as Sepracor Inc., acquired the rights to further develop and commercialize eslicarbazepine acetate in the U.S. and Canadian markets from BIAL.

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 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[®] (lurasidone HCl) tablets, LUNESTA[®] (eszopiclone) tablets, XOPENEX[®] (levalbuterol HCl) inhalation solution, XOPENEX HFA[®] (levalbuterol tartrate) inhalation aerosol, BROVANA[®] (arformoterol tartrate) inhalation solution, OMNARIS[®] (ciclesonide) nasal spray, ZETONNA[®] (ciclesonide) nasal aerosol and ALVESCO[®] (ciclesonide) 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.

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

DSP is a multi-billion dollar, 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 in the Psychiatry & Neurology field, which has been designated as one of the two key therapeutic areas. DSP is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, DSP has more than 7,000 employees worldwide. Additional information about DSP is available through its corporate website at www.ds-pharma.com.

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ⁱ IOM (Institute of Medicine). 2012. Epilepsy across the spectrum: Promoting health and understanding. Washington, DC: The National Academies Press.

ⁱⁱ <http://www.ninds.nih.gov/disorders/epilepsy/epilepsy.htm>

ⁱⁱⁱ <http://www.epilepsyfoundation.org/aboutepilepsy/seizures/partialseizures/index.cfm>

^{iv} http://www.dartmouth.edu/~dons/part_3/chapter_22.html