Sunovion Reports Eslicarbazepine Acetate Meets Primary Endpoint in Two Phase 3 Monotherapy Studies for Partial-onset Seizures in Adults with Epilepsy

Marlborough, Mass., September 17, 2013 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that two completed Phase 3 trials of eslicarbazepine acetate (ESL) as a monotherapy treatment (Studies 093-045 and 093-046) met their primary endpoint. ESL was well-tolerated and demonstrated seizure control rates superior to historical controls in adult patients with partial-onset seizures with or without secondary generalization who were not well-controlled by current antiepileptic drugs (AEDs). ESL is an investigational AED currently under review by the U.S. Food and Drug Administration (FDA) for use as a once-daily adjunctive therapy in the treatment of partial-onset seizures in patients 18 years and older with epilepsy. The efficacy and safety of ESL as an adjunctive or monotherapy treatment for partial-onset seizures in adults living with epilepsy has not yet been established.

“We are pleased to achieve this important milestone in monotherapy, which builds upon our existing data in adjunctive therapy for patients suffering from partial-onset seizures,” said Fred Grossman, D.O., FAPA, Senior Vice President, Clinical Development and Medical Affairs at Sunovion. “Pending the outcome of FDA review of the current New Drug Application (NDA) resubmission for eslicarbazepine acetate as an adjunctive treatment, Sunovion plans to submit these data as part of a supplemental NDA in support of a monotherapy indication.”

Detailed results from Studies 093-045 and 093-046 will be presented at upcoming scientific meetings.

Study Design
The objective of the studies was to evaluate the efficacy and safety of ESL as a monotherapy for treating partial-onset seizures in adults who were not well-controlled by current AEDs. Studies 093-045 and 093-046 were two Phase 3, double-blind, historical-controlled, multicenter randomized trials with identical study designs, which evaluated ESL monotherapy for treating partial-onset seizures in adult patients living with epilepsy. Study 093-045 included 193 patients from 67 study centers across North America. Study 093-046, a global study, included 172 patients across 41 study centers in five countries.

The primary endpoint for both studies was the proportion of patients meeting pre-defined exit criteria (signifying worsening seizure control) 16 weeks post-titration in comparison to historical controls. In both studies, adult patients who were not well-controlled (≥ four partial-onset seizures in the eight weeks prior...
to screening and no four week seizure-free period) with one to two AEDs were gradually converted to monotherapy treatment with ESL and randomized 1:2 to receive ESL 1,200mg QD (n=65 in Study 093-045; n=58 in Study 093-046) or ESL 1,600mg QD (n=128 in Study 093-045; n=114 in Study 093-046).

**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. It 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.

**About Eslicarbazepine Acetate**

Eslicarbazepine acetate is an investigational voltage-gated sodium and T-type calcium channel blocker that has been evaluated in three Phase 3 clinical trials involving more than 1,400 patients with partial-onset seizures worldwide. The initial research and development of eslicarbazepine acetate was performed by BIAL-Portela & Cª, S.A., a privately held Portuguese research based pharmaceutical company. Subsequently, Sunovion Pharmaceuticals Inc., acquired the rights to further develop and commercialize eslicarbazepine acetate in the U.S. and Canadian markets from BIAL. In February 2009, Eisai Europe Limited, a European subsidiary of Eisai Co., Ltd., entered into a license and co-promotion agreement with BIAL, which gave the rights to the former to sell ESL 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 and is currently marketed in Europe under the agreement.

**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® (levlbuterol HCl) inhalation solution, Xopenex HFA® (levlbuterol tartrate) inhalation aerosol, Brovana® (arfomotorer 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](http://www.sunovion.com).

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

Dainippon Sumitomo Pharma Co., Ltd. (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 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 in Japan and overseas offices in 23 countries.
employees worldwide. Additional information about DSP is available through its corporate website at www.ds-pharma.com.

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