

## News Release

**Contacts:** Douglas Reynolds  
President  
Sunovion Pharmaceuticals Canada Inc.  
905-814-9145  
[douglas.reynolds@sunovion.com](mailto:douglas.reynolds@sunovion.com)

Patricia Moriarty  
Senior Director, Corporate Communications  
Sunovion Pharmaceuticals Inc.  
508-787-4279  
[patricia.moriarty@sunovion.com](mailto:patricia.moriarty@sunovion.com)

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### **Sunovion Pharmaceuticals Canada Inc. Announces Health Canada Acceptance for Review of the New Drug Submission of eslicarbazepine acetate as a Once-Daily Adjunctive Therapy for Partial-onset Seizures in Adults with Epilepsy**

**Mississauga, Ontario, September 18, 2013** – Sunovion Pharmaceuticals Canada Inc. (Sunovion) today announced that Health Canada has accepted for review the company's New Drug Submission (NDS) for eslicarbazepine acetate for use as a once-daily adjunctive therapy in the treatment of partial-onset seizures in patients 18 years of age and older with epilepsy. The efficacy and safety of eslicarbazepine acetate as an adjunctive or monotherapy treatment for partial-onset seizures in adults living with epilepsy has not yet been established.

"The acceptance of our eslicarbazepine acetate submission is an important milestone not only for our company, but for thousands of Canadians living with and affected by epilepsy," said Douglas Reynolds, President, Sunovion Pharmaceuticals Canada Inc. "Adequate seizure control remains an unmet medical need for a significant number of patients and Sunovion is committed to providing a treatment option to address this need. If approved, eslicarbazepine acetate may offer adult patients an effective, adjunctive treatment option for better managing partial-onset seizures".

The NDS for eslicarbazepine acetate 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 1,400 patients with partial-onset seizures. In these trials, treatment with eslicarbazepine acetate 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, blurred vision and vertigo.

#### **About Partial-Onset Seizures**

Epilepsy is one of the most common neurological disorders<sup>1</sup> and is characterized by recurrent seizures, with abnormal firing of impulses from nerve cells in the brain<sup>2</sup>. In partial-onset seizures, the abnormal electrical activity begins in specific areas of the brain, but may become more widespread, with symptoms varying according to the affected areas<sup>3,4</sup>.

#### **About Eslicarbazepine Acetate**

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 1,400 patients with partial-

onset seizures worldwide. The initial research and development of eslicarbazepine acetate was performed by BIAL-Portela & C<sup>a</sup>, 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.

**About Sunovion Pharmaceuticals Canada Inc.**

Sunovion Pharmaceuticals Canada Inc., headquartered in Mississauga, Ontario, is a subsidiary of Sunovion Pharmaceuticals Inc. Sunovion Pharmaceuticals Inc., 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)

Sunovion Pharmaceuticals Canada Inc., is focused on the development and commercialization of prescription products in Canada. In addition to commercializing products, our strategy is to license pharmaceutical products that meet the needs of patients and the Canadian health care system, currently focusing on cardiovascular disease, infectious disease and central nervous system (CNS) disorders. More information about Sunovion Pharmaceuticals Canada Inc. is available at [www.sunovion.ca](http://www.sunovion.ca).

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

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 worldwide. Additional information about DSP is available through its corporate website at [www.ds-pharma.com](http://www.ds-pharma.com).

1. Statistics Canada – CANSIM Table 105-1300
2. <http://www.ninds.nih.gov/disorders/epilepsy/epilpesy.htm>
3. <http://www.epilepsyfoundation.org/aboutepilepsy/seizures/partialseizures/index.cfm>
4. [http://www.dartmouth.edu/~dons/part\\_3/chapter\\_22.html](http://www.dartmouth.edu/~dons/part_3/chapter_22.html)

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