

News Release

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Sunovion Pharmaceuticals Canada Inc. Announces Health Canada Approval of APTIOM™ (eslicarbazepine acetate) as a Once-Daily Adjunctive Treatment for Partial-Onset Seizures in Patients with Epilepsy

Mississauga, Ontario, July 11, 2014 – Sunovion Pharmaceuticals Canada Inc. (Sunovion) today announced that Health Canada approved APTIOM™ (eslicarbazepine acetate) for use as a once-daily adjunctive therapy for the treatment of partial-onset seizures in patients with epilepsy who are not satisfactorily controlled with conventional therapy. APTIOM™ is not indicated for use in patients under 18 years of age.

Epilepsy is one of the most common neurological disorders and according to Epilepsy Canada, it affects 0.6% of the population and each year approximately 15,500 people learn they have epilepsy. Partial-onset seizures are the most prevalent seizure type, accounting for 60% of new epilepsy diagnoses¹ and approximately one third of patients do not have adequate seizure control⁵.

The approval of APTIOM™ is based on three Phase 3 randomized, double-blind, placebo-controlled, safety and efficacy trials (Studies BIA-2093-301, BIA-2093-302 and BIA-2093-304), which included more than 1,400 people living with partial-onset seizures inadequately controlled by one to three concomitant AEDs (including carbamazepine, lamotrigine, valproic acid and levetiracetam). In these global studies, treatment with APTIOM™ demonstrated statistically significant reductions in standardized seizure frequency versus placebo, and significantly more APTIOM™ treated patients experienced seizure frequency reduction of 50% or more from baseline (41% compared to 22% for placebo-treated patients).

The most frequently reported adverse reactions in patients taking APTIOM™ were dizziness, somnolence, headache, nausea, diplopia, vomiting, fatigue, ataxia, vision blurred, and vertigo.

“The approval of APTIOM™ 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.”

About Partial-Onset Seizures

Epilepsy is a chronic neurological condition characterized by recurrent seizures resulting from abnormal firing of impulses from nerve cells in the brain². 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^{3,4}.

About APTIOM™

APTIOTM, a voltage-gated sodium channel inhibitor, is a prescription medicine approved for use as adjunctive treatment of partial-onset seizures. Treatment with APTIOTM should be initiated at 400 mg once daily. After one week, dosage may be increased to the recommended maintenance dosage of 800 mg once daily. Some patients may benefit from the maximum recommended maintenance dosage of 1,200 mg once daily, although this dosage is associated with an increase in adverse reactions. The maximum dose of 1,200 mg daily should only be initiated after the patient has tolerated 800 mg daily for at least a week. For some patients, treatment may be initiated at 800 mg once daily if the need for additional seizure reduction outweighs an increased risk of adverse reactions during initiation. The initial research and development of eslicarbazepine acetate was performed by BIAL, a privately held Portuguese research-based pharmaceutical company. Subsequently, Sunovion acquired the rights under an exclusive license to further develop and commercialize eslicarbazepine acetate in the U.S. and Canadian markets from BIAL. Eslicarbazepine acetate was approved on November 8, 2013, by the U.S. FDA as adjunctive treatment of partial-onset seizures.

In February 2009, Eisai Europe Limited, a European subsidiary of Eisai Co., Ltd. (Eisai), entered into a license and co-promotion agreement with BIAL, which gave the rights to Eisai to sell eslicarbazepine acetate under the trade name Zebinix[®] in Europe. 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 Canada Inc.

Sunovion Pharmaceuticals Canada Inc. is focused on the development and commercialization of prescription products in Canada. In addition to commercializing Sunovion Pharmaceuticals Inc.'s 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.

Sunovion Pharmaceuticals Canada Inc., a subsidiary of the U.S. based Sunovion Pharmaceuticals Inc., is headquartered in Mississauga, Ontario. Sunovion Pharmaceuticals Inc., an indirect, wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at www.sunovion.com.

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is a top-ten listed pharmaceutical company in Japan with a diverse portfolio of pharmaceutical, animal health and food and specialty products. Sumitomo Dainippon Pharma aims to produce innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

APTIOTM is under license from BIAL. 

1. <http://www.epilepsy.ca/en-CA/Facts/Epilepsy-Facts.html>
2. <http://www.ninds.nih.gov/disorders/epilepsy/epilepsy.htm>
3. <http://www.epilepsyfoundation.org/aboutepilepsy/seizures/partialseizures/index.cfm>
4. http://www.dartmouth.edu/~dons/part_3/chapter_22.html
5. Kwan P, Brodie MJ. N Eng J Med. 2000; 342:314-319

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