

## News Release

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### **Sunovion Pharmaceuticals Canada Inc. Announces Health Canada Approval of Once-Daily LATUDA™ (lurasidone HCl) for the Treatment of Patients with Schizophrenia**

*- NDS Included 48 Clinical Studies Involving More Than 2,900 Subjects Treated With Lurasidone*

**Mississauga, Ontario, June 15, 2012** – Sunovion Pharmaceuticals Canada Inc. today announced that the New Drug Submission (NDS) for LATUDA™ (lurasidone HCl), for the treatment of adult patients with acute schizophrenia has been approved by Health Canada. “We are pleased that LATUDA has achieved this significant milestone,” said Douglas Reynolds, President, Sunovion Pharmaceuticals Canada Inc. “More importantly, LATUDA will provide patients in Canada suffering from schizophrenia a new option that can help support their treatment goals for this serious and complex disorder.”

“Schizophrenia is a disease that is complex and a challenge to treat effectively,” said Dr. Philip Tibbo, Psychiatrist at Capital District Health Authority and Director of the Nova Scotia Early Psychosis Program in Halifax. “Each person suffering from schizophrenia is different, and new treatment options are always needed. Effective, individualized treatment that offers a balance between efficacy, safety and tolerability can help support each patient to reach their treatment goals.”

“It is important to always have a number of treatment options available for those living with schizophrenia.” said Chris Summerville, Chief Executive Officer of the Schizophrenia Society of Canada. “Schizophrenia is treatable, and individual patient recovery is possible. More choice in finding the right medication is vital, and having more treatment options accessible to patients by all private and public drug plans in Canada can help greatly in supporting their recovery process.”

#### **About Schizophrenia**

Schizophrenia is a chronic, disabling disorder that is characterized by symptoms such as hallucinations, delusions, disorganized thinking, lack of emotion, lack of energy, as well as problems with memory, attention and the ability to plan, organize and make decisions. This disease affects approximately one percent of the population, which translates to more than 335,000 Canadians<sup>1</sup>. The goal of treatment is to reduce symptoms, achieve remission, and facilitate illness recovery. While there are many treatment options available, each patient responds to their medications differently. A key obstacle is the ability to tolerate medications and unfortunately treatment discontinuation in this disease is as high as 40-50%<sup>2</sup>. Discontinuation is only partly due to intolerability; lack of efficacy plays the biggest role. Effective treatment for each patient requires the right balance of efficacy, safety and tolerability.

### **About LATUDA**

LATUDA (lurasidone HCl) is a new medication in the atypical antipsychotic class that has been approved by Health Canada for the acute treatment of adult patients with schizophrenia.

LATUDA has been extensively studied through 48 clinical studies involving more than 2,900 lurasidone-treated subjects. The efficacy of LATUDA was demonstrated in five six-week, placebo-controlled studies, involving hospitalized patients with schizophrenia. The efficacy of LATUDA for long-term use, that is, for more than 6 weeks, has not been systemically evaluated in controlled studies. LATUDA was associated with low rates of change in metabolic parameters versus placebo. Further, the pharmacokinetic properties provide once-daily dosing. The most common adverse events in patients treated with LATUDA are somnolence, akathisia, nausea, and parkinsonism.

### **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](http://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 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)**

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 CNS field, which has been designated as the key therapeutic area and will also focus in on other specialty disease categories with significant unmet medical needs, which are designated as frontier 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).

LATUDA™ is a registered trademark of Dainippon Sumitomo Pharma Co., Ltd.

<sup>1</sup> Public Health Agency of Canada, Available at: [http://www.phac-aspc.gc.ca/publicat/miic-mmacc/chap\\_3-eng.php](http://www.phac-aspc.gc.ca/publicat/miic-mmacc/chap_3-eng.php). Accessed June 11, 2012.

<sup>2</sup> IMS Brogan, March 2012

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