News Release

April 3, 2014

Dainippon Sumitomo Pharma Co., Ltd.

Dainippon Sumitomo Pharma Announces Health Canada Approval of LATUDA® (lurasidone HCl) as Monotherapy and Adjunctive Therapy in Patients with Bipolar Depression

Osaka, Japan, April 3, 2014 – Dainippon Sumitomo Pharma Co., Ltd. ("DSP") (Head Office: Osaka, Japan; President: Masayo Tada) announced that Health Canada approved on March 31 (local time) the use of LATUDA® (lurasidone HCl) as monotherapy or as adjunctive therapy with lithium or valproate for the treatment of depressive episodes associated with bipolar I disorder. The antipsychotic agent LATUDA® has been marketed for the treatment of schizophrenia in Canada by Sunovion Pharmaceuticals Canada Inc., a subsidiary of the U.S.-based Sunovion Pharmaceuticals Inc. The application for the additional indications was submitted in August 2012 for review by the Health Canada.

Two double-blind, placebo-controlled, six-week Phase III clinical studies (PREVAIL 1 and PREVAIL 2) supported the new indication. Both studies showed that treatment with LATUDA® resulted in statistically significant and clinically meaningful reductions in the major endpoint of the Montgomery-Asberg Depression Rating Scale (MADRS) total score at Week 6, with significant separation from placebo observed as early as Week 2 of treatment. In both studies, the patients treated with LATUDA® experienced low rates of change in weight, body mass index (BMI), lipid parameters and measures of glycemic control.

DSP hopes that LATUDA® will contribute to the treatment of patients suffering from depressive symptoms associated with bipolar I disorder (bipolar depression) in Canada.

About Bipolar Disorder

It is estimated that more than 29 million people suffer from bipolar disorder worldwide.

Bipolar I disorder is characterized by at least one lifetime manic or mixed episode; often individuals have also had one or more major depressive episodes. When symptomatic, most people with bipolar disorder spend more time being depressed, rather than manic. Bipolar depression refers to the depressive phase of bipolar disorder. Symptoms of a major depressive episode associated with bipolar depression include: depressed mood, loss of interest or pleasure in activities, significant weight loss, insomnia, fatigue, feelings of worthlessness, diminished ability to concentrate and recurrent thoughts of death or suicide attempt. Bipolar disorder can also double a person's risk of early death from a range of medical conditions, including obesity, diabetes and cardiovascular disease. Bipolar disorder is the sixth leading cause of disability worldwide and is among the top 10 leading causes of disability in the United States.

About LATUDA®

Lurasidone HCl is a novel atypical antipsychotic developed originally by DSP. Lurasidone was approved by the U.S. Food and Drug Administration (FDA) in October 2010 for schizophrenia, and it was launched in February 2011 under the brand name LATUDA®. The FDA approved additional indications for the use of LATUDA® in June 2013 for the treatment of bipolar I disorder (bipolar depression). In Canada, the New Drug Submission (NDS) for LATUDA® was filed in June 2011 and was approved by Health Canada in June 2012 for the treatment of schizophrenia. The market launch in Canada was in September 2012.

About Sunovion Pharmaceuticals Canada Inc.

Company name:	Sunovion Pharmaceuticals Canada Inc.
Headquarters:	Mississauga, Ontario, Canada
President:	Douglas Reynolds
Line of business:	Development and marketing of pharmaceuticals as a subsidiary of U.S.-based Sunovion Pharmaceuticals Inc. For further details, please visit its official website at: http://www.sunovion.ca

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