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Dainippon Sumitomo Pharma Co., Ltd. Daiichi Sankyo Co., Ltd.

## Dainippon Sumitomo Pharma and Daiichi Sankyo Cooperate on Lurasidone, an Atypical Antipsychotic Agent, in Four South American Countries

Dainippon Sumitomo Pharma Co., Ltd. ("DSP") (Head Office: Osaka, Japan; President: Masayo Tada) and Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") (Head Office: Tokyo, Japan; President: Joji Nakayama) announced that they have entered into a license agreement for the commercialization of lurasidone hydrochloride ("lurasidone"), an atypical antipsychotic agent discovered by DSP, in Brazil and Venezuela. In addition, DSP has granted Daiichi Sankyo the option right for the commercialization for lurasidone in Argentina and Colombia.

Under the terms of the agreement, Daiichi Sankyo will file applications for marketing approval of lurasidone in the licensed countries through its local subsidiaries, and commercialize lurasidone after obtaining appropriate approval within those countries.

For DSP, lurasidone is a product with global strategic importance. In parallel to an early maximization of the ongoing sales of lurasidone in the U.S. and Canada, DSP seeks to expand its sales to Europe, Japan, China, Southeast Asia, Australia and South America, with a view to realizing the full potential of the lurasidone business.

For Daiichi Sankyo, the fast-growing South American market is of great importance, and the company has already established sales networks of its own in Brazil and Venezuela. It is expected that the addition of lurasidone to its product line will accelerate Daiichi Sankyo's further business expansion in the region.

The two companies cooperatively aim for the earliest possible approval and commercialization of lurasidone in South American market to make the product available to as many patients as soon as possible.

## About lurasidone

Lurasidone is an atypical antipsychotic, developed originally by DSP with an affinity for dopamine D2, serotonin 5-HT2A and serotonin 5-HT7 receptors where it has antagonist effects. In addition, lurasidone is a partial agonist at the serotonin 5-HT1A receptor and has no appreciable affinity for histamine or muscarinic receptors.

Lurasidone was approved for the treatment of adults with schizophrenia by the United States Food and Drug Administration in October 2010 and by Health Canada in June 2012. It was launched as brand name Latuda<sup>®</sup> in the United States in February, 2011 and in Canada in September, 2012 through DSP's subsidiary Sunovion Pharmaceuticals Inc. Lurasidone also received approval for the treatment of adults with depressive episodes associated with bipolar I disorder (bipolar depression) as monotherapy and adjunctive therapy with lithium or valproate in the US (June 2013) and Canada (March 2014).

With respect to Europe, the European Medicines Agency (EMA) accepted the Marketing Authorization Application in September 2012 for lurasidone for the treatment of schizophrenia submitted by a European subsidiary of Takeda Pharmaceutical Company, Limited ("Takeda"), DSP's development and commercialization partner for Europe. Latuda® will be marketed in the UK by Sunovion Pharmaceuticals Europe Ltd., a subsidiary of DSP, and across Europe by Takeda subsidiaries. In Switzerland, Lurasidone was launched for the treatment of schizophrenia in adults in September 2013 through Takeda Pharma AG, is a wholly owned subsidiary of Takeda.

In Japan, Phase III clinical study is underway for the treatment of schizophrenia and of bipolar I disorder (bipolar depression) by DSP.

In Australian, Latuda® was approved for the treatment of adults with schizophrenia in March 2014.

In Taiwan, its authorities accepted the application for the treatment of adults with schizophrenia, development in the Chinese and Southeast Asian markets is planned.

## **Contacts:**

Corporate Communications

Dainippon Sumitomo Pharma

TEL: +81-6-6203-1407 (Osaka), +81-3-5159-3300 (Tokyo)

Corporate Communications Department

Daiichi Sankyo

Telephone: +81-3-6225-1126 (media relations)

+81-3-6225-1125 (investor relations)