

July 31, 2019

Sumitomo Dainippon Pharma Co., Ltd.

**Sumitomo Dainippon Pharma Submits New Drug Application for Approval of
Manufacturing and Marketing for Lurasidone in Japan for the Treatment of
Schizophrenia and Bipolar Depression**

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced today that it has submitted a new drug application for approval of manufacturing and marketing for lurasidone hydrochloride (generic name) in Japan for the treatment of schizophrenia and bipolar depression.

Lurasidone is an atypical antipsychotic agent that is believed to have an affinity for dopamine D₂, serotonin 5-HT_{2A} and serotonin 5-HT₇ receptors where it has antagonist effects. In addition, lurasidone is a partial agonist at the serotonin 5-HT_{1A} receptor. Lurasidone is a core product of Sumitomo Dainippon Pharma group, sold under the product name Latuda® in the United States and other countries, with revenue of 184.5 billion yen posted in North America in FY2018.

The application in Japan involves the data of a Phase 3 study (JEWEL study) for lurasidone, targeting patients with schizophrenia, and another Phase 3 study (ELEVATE study) targeting patients with bipolar I depression. Preliminary results of the JEWEL study and the ELEVATE study have previously been announced in press releases dated January 10, 2019 and June 9, 2017, respectively.

Upon approval of lurasidone in Japan, Sumitomo Dainippon Pharma seeks to contribute greatly to the treatment of schizophrenia and bipolar depression by providing new treatment options for both diseases.

<Reference information>

About lurasidone hydrochloride

Lurasidone hydrochloride is an atypical antipsychotic agent that is believed to have an affinity for dopamine D₂, serotonin 5-HT_{2A} and serotonin 5-HT₇ receptors where it has antagonist effects. In addition, lurasidone is a partial agonist at the serotonin 5-HT_{1A} receptor and has no appreciable affinity for histamine H₁ or muscarinic M₁ receptors.

Lurasidone was approved for the treatment of schizophrenia in the United States in 2010, in Canada in 2012, in Switzerland in 2013, in Europe and Australia in 2014, in Taiwan, Russia, Singapore, Thailand and Hong Kong in 2016, in Brazil and UAE in 2017, in Macao and Venezuela in 2018, and in China in 2019, and also was approved for the treatment of bipolar I depression in

the United States in 2013, in Canada in 2014, and in Russia, Brazil and Taiwan in 2017.

About schizophrenia

Schizophrenia is a chronic, serious and often severely disabling brain disorder. It is estimated to affect approximately 800,000 people in Japan. The condition includes symptoms such as hallucinations and delusions, unusual or dysfunctional ways of thinking, agitated body movements, reduced expression of emotions and poor focus, memory or executive functioning.

About bipolar depression

Bipolar disorder is a chronic and serious disease characterized by repeated cycles of manic and depressive episodes. It is estimated to affect approximately 220,000 people in Japan. When symptomatic, most patients spend more time being depressed, rather than manic. Symptoms of 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.

About JEWEL (Japan and Europe Working to Evaluate Lurasidone) Study

The JEWEL Study was a multi-center, placebo-controlled, randomized, double-blind Phase 3 study with patients in several countries including Japan for the treatment of schizophrenia.

Using the pre-specified primary analysis in the ITT (Intent to Treat) population (N=478), the lurasidone 40 mg/day group (245 patients) demonstrated statistically significant improvement compared to the placebo group (233 patients) in the primary endpoint of change from baseline in the PANSS (Positive and Negative Syndrome Scale) *¹ total score after 6 weeks of study treatment [-19.3 in the lurasidone 40 mg/day group and -12.7 in the placebo group (p<0.001)]. In addition, the lurasidone 40 mg/day group demonstrated statistically significant improvement compared to the placebo group on the change from baseline of the Clinical Global Impressions Severity scale (CGI-S) *² after 6 weeks, a secondary efficacy endpoint.

*¹ Positive and Negative Syndrome Scale (PANSS): An evaluation scale mainly intended to capture the overall mental status of schizophrenia. It consists of a total of 30 symptom items including 7 positive items, 7 negative and 16 general psychopathology items. For each item the mental status is rated in a 7-point scale from 1 (no symptoms) to 7 (most serious).

*² Clinical Global Impressions-Severity of Illness Scale (CGI-S): A 7-point scale to rate the severity of illness from 1 (normal) to 7 (extremely ill).

About ELEVATE (Establishing Lurasidone: EVAluation of its Antidepressant Treatment Effect) Study

The ELEVATE Study was a multi-center, placebo-controlled, randomized, double blind Phase 3 study with patients in Japan, Asia and a part of Europe for the treatment of bipolar I depression.

By pre-specified primary analysis in the ITT population (N=522), statistically significant

improvement was demonstrated for the lurasidone 20 - 60 mg/day group (182 patients) compared to the placebo group (171 patients) at the primary endpoint, namely, the change from baseline in MADRS ^{*3} total score after 6 weeks of study treatment [20 - 60 mg/day group -13.6, placebo group -10.6 (adjusted p=0.007)]. The lurasidone 80 - 120 mg/day group (169 patients, -12.6) also demonstrated improvement compared to placebo group (171 patients) but the difference was not statistically significant (adjusted p=0.057).

^{*3} MADRS (Montgomery-Åsberg Depression Rating Scale): A rating scale that assesses the severity of depressive symptoms. It comprises the following 10 items: apparent sadness, reported sadness, inner tension, reduced sleep, reduced appetite, concentration difficulties, lassitude, inability to feel, pessimistic thoughts, and suicidal thoughts. Each item is assessed on a 7-point severity scale from 0 to 6, with higher ratings indicating more severe symptoms.

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