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Sumitomo Dainippon Pharma Co., Ltd.

**Sumitomo Dainippon Pharma Announces Positive Topline Results from a Phase III Clinical Study (JEWEL Study) of Lurasidone, an Atypical Antipsychotic Agent, in the Treatment of Patients with Schizophrenia**

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura hereinafter called “Sumitomo Dainippon Pharma”) announced today that topline results from a Phase III clinical study (JEWEL study, “this study”) evaluating lurasidone hydrochloride (generic name, “lurasidone”), an atypical antipsychotic in the treatment of patients with schizophrenia met its primary endpoint and demonstrated a favorable tolerability profile of lurasidone. The Phase III study was conducted to support regulatory approval in Japan.

This study was a multi-center, placebo-controlled, randomized, double-blind, 6-week study intended to evaluate the efficacy and safety of lurasidone 40 mg/day vs. placebo, involving 483 patients with schizophrenia.

Using the pre-specified primary analysis in the ITT (Intent to Treat) population (n=478), the lurasidone group (245 patients) demonstrated statistically significant improvement compared to the placebo group (233 patients) in the primary endpoint of change from baseline of the PANSS (Positive and Negative Syndrome Scale) \*<sup>1</sup> total score after 6 weeks of study treatment [-19.3 in the lurasidone group and -12.7 in the placebo group (p<0.001)].

In addition, the lurasidone group demonstrated statistically significant improvement compared to the placebo group on the change from baseline of the Clinical Global Impressions Severity scale (CGI-S)\*<sup>2</sup> after 6 weeks, a secondary efficacy endpoint.

In this study, lurasidone was generally well-tolerated, and adverse events (AEs) observed in the lurasidone group were generally mild and consistent with prior studies of lurasidone in patients with schizophrenia. The incidences of AEs in the lurasidone group and the placebo group were 47.0% and 51.1%, respectively. Fewer patients discontinued the study treatment in the lurasidone group (19.4%) than in the placebo group (25.4%). Similar proportions of patients in the lurasidone and placebo groups discontinued due to AEs (5.7% and 6.4%, respectively).

Based on the results of this study, as well as the completed Phase III study involving patients with bipolar I depression\*<sup>3</sup>, Sumitomo Dainippon Pharma plans to submit new drug applications for approval of manufacturing and marketing of lurasidone for the treatment of patients with schizophrenia and bipolar depression in Japan, in the first half of FY2019.

\*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 seven positive items, seven negative and 16 general psychopathology items. For each item the mental status is rated in a scale of 7 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).

\*3 Topline results from a Phase III study in patients with bipolar I depression were announced in the press release as of June 9, 2017.

<Reference information>

#### About JEWEL Study

The JEWEL (Japan and Europe Working to Evaluate Lurasidone) Study was a multi-center, placebo-controlled, randomized, double-blind, Phase 3 study to evaluate the efficacy and safety of 6-week administration of lurasidone 40 mg/day in comparison with placebo with patients in several countries including Japan diagnosed with schizophrenia according to the DSM-IV-TR\*4 standard. A total of 483 patients were randomized into two groups: lurasidone 40 mg/day (247 patients) and placebo (236 patients). The primary endpoint was change from the baseline of the PANSS total score after 6 weeks of administration and the secondary endpoints were changes from the baseline of the PANSS total score and CGI-S at each evaluation points and others.

An open-label, long-term treatment study following the above-mentioned 6-week study is underway to further evaluate the safety and efficacy of lurasidone through a 12-week administration of lurasidone (40 mg/day – 80 mg/day, flexible dose) in patients with schizophrenia.

\*4 DSM-IV-TR: A diagnostic and statistical manual/standard of mental disorders as defined by the American Psychiatric Association (APA)

#### About lurasidone

Lurasidone is an atypical antipsychotic agent that is believed to have an affinity for dopamine D<sub>2</sub>, serotonin 5-HT<sub>2A</sub> and serotonin 5-HT<sub>7</sub> receptors where it has antagonist effects. In addition, LATUDA is a partial agonist at the serotonin 5-HT<sub>1A</sub> receptor and has no appreciable affinity for histamine H<sub>1</sub> or muscarinic M<sub>1</sub> receptors.

Lurasidone has been 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, and in Brazil and UAE in 2017, and also has been approved for the treatment of bipolar I depression in the United States in 2013, in Canada in 2014, in Russia, Brazil and Taiwan in 2017. Sumitomo Dainippon Pharma is aiming to submit new drug applications for approval of the treatment of schizophrenia and bipolar depression in Japan during the first half of FY 2019 and submitted the New Drug Application for the treatment of schizophrenia in China.

### About Schizophrenia

Schizophrenia is a chronic, serious and often severely disabling brain disorder. It is estimated to affect 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.

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