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Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Topline Results from a Phase 3 Study of Lurasidone, an Atypical Antipsychotic Agent, in the Treatment of Patients with Bipolar I Depression

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; President: Masayo Tada) announced today that a Phase 3 study evaluating lurasidone hydrochloride (generic name, "lurasidone"), an atypical antipsychotic, in the treatment of patients with bipolar I depression met its primary endpoint in the 20 - 60 mg/day group. The Phase 3 study was conducted for regulatory approval in Japan.

The study was a multi-center, placebo-controlled, randomized, double blind 6-week study intended to evaluate the efficacy and safety of flexibly dosed lurasidone, involving 525 patients with bipolar I depression, who were randomized to receive lurasidone 20 - 60 mg/day (n=184) or 80 - 120 mg/day (n=169), or placebo (n=172).

By pre-specified analysis in the ITT population (n=522), statistically significant improvement was demonstrated for the lurasidone 20 - 60 mg/day group compared to the placebo group at primary endpoint, namely, the change from baseline in MADRS* 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 (-12.6) also demonstrated improvement compared to placebo but the difference was not statistically significant (adjusted p=0.057).

The most common TEAEs reported in the lurasidone treatment groups were consistent with lurasidone's previous studies, and thus no major issue was found in terms of tolerability with limited effects on weight and metabolic parameters. The incidences of TEAEs in the 20 - 60mg mg/day, 80 - 120 mg/day and placebo groups were 53.3%, 59.2% and 45.9%, respectively. There were no apparent differences in incidences of serious TEAEs among treatment groups.

Based on the results of this study, as well as the ongoing Phase 3 studies in schizophrenia and bipolar maintenance, Sumitomo Dainippon Pharma is planning to submit an application for approval of manufacturing and marketing of lurasidone in Japan in FY2019.

*MADRS (Montgomery-Åsberg Depression Rating Scale): A rating scale that assesses a range of symptoms most frequently observed in patients with major depression. 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 seven-point severity scale (0 to 6, with higher ratings indicating more

severe symptoms).

<Reference information>

【About Lurasidone】

Lurasidone is an atypical antipsychotic created originally by Sumitomo Dainippon Pharma, characterized by a unique chemical structure and 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 has been approved for the treatment of schizophrenia in the United States in 2010, in Canada in 2012, in Switzerland in 2013, in E.U. and Australia in 2014, and in Taiwan, Russia and Singapore in 2016, and also has been approved for the treatment of bipolar I depression in the United States in 2013, in Canada in 2014. Sumitomo Dainippon Pharma is conducting Phase 3 studies with a view to obtaining approvals of lurasidone for the treatment of schizophrenia and bipolar maintenance in Japan and submitted the New Drug Application for the treatment of schizophrenia in China.

【About bipolar I disorder】

Bipolar I disorder is characterized by at least one lifetime manic or mixed episode within bipolar disorder; 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 I depression refers to the depressive phase of bipolar disorder. Symptoms of a major depressive episode associated with bipolar I 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 a phase 3 study in patients with bipolar I depression】

The study was a multi-center, placebo-controlled, randomized, double blind study to evaluate the efficacy and safety of 6-week administration of lurasidone 20 - 60 mg/day and 80 - 120 mg/day in comparison with placebo with patients in Japan, Asia and a part of Europe diagnosed with bipolar I depression based on DSM-IV-TR*. A total of 525 patients were assigned to lurasidone 20 - 60 mg/day (n=184), 80 - 120 mg/day (n=169) and placebo (n=172) treatment. The primary endpoint was the change from the baseline of the MADRS total score after 6 weeks of study treatment.

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

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