

December 25, 2014

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Preliminary Findings from a Phase III Clinical Study (PASTEL Study) of Lurasidone, an Atypical Antipsychotic Agent, in the Treatment of Patients with Schizophrenia

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; President: Masayo Tada; Securities Code: 4506, First Section of TSE) announced today preliminary findings from a Phase III clinical study (PASTEL study) conducted for application for approval in Japan of lurasidone hydrochloride (generic name, "lurasidone"), an atypical antipsychotic in the treatment of patients with schizophrenia.

The study was a multi-center, placebo-controlled, randomized, double-blind 6-week study intended to evaluate the efficacy and safety of lurasidone, involving 457 patients with schizophrenia in three groups (about 150 patients in each group) of lurasidone 40 mg/day, lurasidone 80 mg/day and placebo.

The primary endpoint of the study was change from the baseline of the Positive and Negative Syndrome Scale (PANSS)^{*1} total score, which was used to assess the efficacy of lurasidone compared to placebo. As a secondary endpoint, change from baseline in the Clinical Global Impressions-Severity of Illness Scale (CGI-S)^{*2} was evaluated.

By pre-specified analysis in modified ITT population^{*3} (n=430), statistically significant improvement was demonstrated for lurasidone 40 mg/day group (-18.1) compared to the placebo group (-13.0) in the primary endpoint, namely, the change from baseline of the PANSS total score after 6 weeks of administration. The lurasidone 80 mg/day group (-17.5) also demonstrated improvement compared to placebo but the difference was not statistically significant.

At the same time, by additional analysis in the ITT population (n=446), statistically significant improvements were demonstrated for lurasidone 40 mg/day (-17.8) and lurasidone 80 mg/day (-17.3) groups compared to the placebo group (-12.1) in the primary endpoint, namely, the change from baseline of the PANSS total score after 6 weeks of administration. Sumitomo Dainippon Pharma believes data from this population best represents the efficacy of lurasidone in patients with schizophrenia and also will be submitted for an application for approval of production and marketing of lurasidone in Japan.

In terms of the secondary endpoint, namely, the change from baseline of the CGI-S after 6 weeks, no statistically significant improvement was observed for lurasidone 40 mg/day group and lurasidone 80 mg/day group compared to the placebo group.

Adverse events observed in the lurasidone groups were generally mild and consistent with other studies that utilized lurasidone at the same doses in patients with schizophrenia. Incidence of

adverse events was lurasidone 40 mg/day: 68.7%, lurasidone 80 mg/day: 69.5% and placebo: 64.2%. The discontinuation ratio of the lurasidone groups (27.2%) was lower than that of placebo group (27.6%), and the discontinuation for reason of adverse events was few (lurasidone groups: 7.2%, placebo group: 10.6%).

PASTEL is the seventh study demonstrating the efficacy and safety of lurasidone within dose range of 40-160 mg/day in patients with schizophrenia and based on the PASTEL results, Sumitomo Dainippon Pharma intends to proceed with necessary preparations for submitting an application for approval of production and marketing of lurasidone in Japan. The study will also support applications that are either under review or will be submitted within the near future in Asia.

Financial impact of this development on the consolidated performance of the Company's fiscal year ending on March 31, 2015 is minor.

*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 Any scores that were evaluated within 12 hours after the use of lorazepam or hypnotic drugs were excluded.

<Reference information>

About PASTEL Study

The PASTEL (Pan Asia Study To Evaluate Lurasidone) Study was a multi-center, placebo-controlled, randomized, double-blind study to evaluate the efficacy and safety of 6-week administration of lurasidone 40 mg/day and 80 mg/day in comparison with placebo with patients in Japan, Korea, Taiwan and Malaysia diagnosed with schizophrenia according to the DSM-IV-TR^{*4} standard. A total of 457 patients were grouped into lurasidone 40 mg/day (150 patients), lurasidone 80 mg/day (155 patients) and placebo (152 patients). The primary endpoint was change from the baseline of the PANSS total score after 6 weeks of administration and the secondary endpoint was change from the baseline of the CGI-S after 6 weeks of administration. An open-label, long-term administration continuation study is underway to further evaluate the safety and efficacy of lurasidone through a 26-week administration of lurasidone 40 mg/day or lurasidone 80 mg/day in patients with schizophrenia.

*4 DSM-IV-TR: The manual and criteria defined by the American Psychiatric Association for classification and diagnosis of mental disorders.

About lurasidone

Lurasidone is an atypical antipsychotic, developed originally by Sumitomo Dainippon Pharma with 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 or muscarinic receptors.

Lurasidone was approved for the treatment of adults with schizophrenia in the United States in October 2010, in Canada in June 2012, in Switzerland in August 2013 and in Europe and in Australia in March 2014.

It was launched as brand name LATUDA® in the United States in February 2011 through one of our U.S. subsidiaries Sunovion Pharmaceuticals Inc., and in Canada in September 2012 and in the U.K. in August 2014, respectively by Sunovion's Canadian and U.K. subsidiaries, Sunovion Pharmaceuticals Canada Inc. and Sunovion Pharmaceuticals Europe Limited. In Switzerland, lurasidone was launched in September 2013 also by the brand name LATUDA® through Takeda Pharma AG, a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, a development and commercialization partner.

About schizophrenia

Schizophrenia is a mental disorder which is said to be affecting some 700,000 patients in Japan. It is known as a mental disorder which expresses a variety of conditions including positive symptoms such as hallucinations and delusions, negative symptoms such as flat emotions, diminished thinking, loss of drive, as well as cognitive impairments such as reduced attentiveness, disturbance of information-processing capacity.

Contact:

Corporate Communications

Sumitomo Dainippon Pharma

TEL: +81-6-6203-1407 (Osaka)

+81-3-5159-3300 (Tokyo)