Sumitomo Dainippon Pharma

News Release

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Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Approval of Atypical Antipsychotic Agent, LATUDA® Tablets in Japan

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced today that a new drug application for LATUDA® Tablets (generic name: lurasidone hydrochloride, hereinafter, "this Drug"), an atypical antipsychotic agent for schizophrenia and bipolar depression, was approved in Japan on March 25. Sumitomo Dainippon Pharma will launch this Drug after NHI drug price listing.

Sumitomo Dainippon Pharma submitted a new drug application for approval of manufacturing and marketing for LATUDA® Tablets on July 31, 2019, based mainly on the results of multinational phase 3 studies (PASTEL study and JEWEL study) and a long-term extension study (JEWEL extension study) in schizophrenia patients and those of a multinational phase 3 study (ELEVATE study) in bipolar I depression patients. As this Drug was prior assessment consultation item evaluated before approval application based on the data planned for submission, its new drug application was approved after a review period of around 8 months, which is shorter than usual.

This Drug is an atypical antipsychotic agent with an original chemical structure created by Sumitomo Dainippon Pharma that has antagonist effects for dopamine D_2, serotonin 5-HT_{2A}, and serotonin 5-HT_7 receptors. It is also a partial agonist for serotonin 5-HT_{1A} receptors but has no appreciable affinity for histamine H_1 or muscarinic M_1 receptors.

Since this Drug was approved in the U.S. in October 2010 for schizophrenia in adults, it has been approved for this indication in 47 countries and regions including the U.S. and European countries. It has also been approved in a total of 7 countries and regions, including the U.S., for depressive episode associated with bipolar I disorder. In foreign guidelines, it is considered to be an antipsychotic with low risk of weight gain, and is recommended as one of first-choice drugs for bipolar depression where there are few therapy options.

By providing a new treatment option with this approval, Sumitomo Dainippon Pharma aims to make a contribution to the treatment of schizophrenia and bipolar depression in Japan.

References

About PASTEL Study

The PASTEL 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 and 80 mg/day in comparison with placebo with patients in several countries including Japan diagnosed for schizophrenia.

Based on the pre-specified analysis in modified ITT population*1 (n=439), improvements were demonstrated both for lurasidone 40 mg/day group (n=145, -17.9) and 80 mg/day group (n=152, -17.3) compared to the placebo group (n=142, -13.1) in the primary endpoint, namely, the change from baseline of the PANSS (Positive and Negative Syndrome Scale) *2 total score after 6 weeks of administration. In neither group, however, the difference was statistically significant.
At the same time, by additional analysis in the ITT (Intent to Treat) population (n=450), statistically significant improvements were demonstrated for lurasidone 40 mg/day (n=148, -17.7) and 80 mg/day (n=154, -16.8) groups compared to the placebo group (n=148, -11.9) in the primary endpoint, namely, the change from baseline of the PANSS total score after 6 weeks of administration. The result of the PASTEL study has previously been announced in press releases dated December 25, 2014 and April 24, 2015.

*1 Any scores that were evaluated within 12 hours after the use of lorazepam or hypnotic drugs were excluded.
*2 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).

About JEWEL Study and JEWEL extension 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.
Based on the pre-specified primary analysis in the ITT population (n=478), the lurasidone 40 mg/day group (n=245) demonstrated statistically significant improvement compared to the placebo group (n=233) in the primary endpoint of change from baseline in the PANSS total score after 6 weeks of study treatment (-19.3 in the lurasidone 40 mg/day group and -12.7 in the placebo group). 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) *3 after 6 weeks, a secondary efficacy endpoint. The result of the JEWEL study has previously been announced in press releases dated January 10, 2019.
The JEWEL extension study was a long-term extension study from JEWEL study to evaluate the long-term safety and effectiveness of lurasidone for schizophrenia. Rollover patients (n=289) who completed the JEWEL study and consented to join the extension study were treated with lurasidone 40mg/day or 80mg/day for 12 weeks and 235 patients completed JEWEL extension study.

*3 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 Study
The ELEVATE Study was a multi-center, placebo-controlled, randomized, double blind Phase 3 study with patients in several countries including Japan 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 (n=182) compared to the placebo group (n=171) at the primary endpoint, namely, the change from baseline in MADRS *4 total score after 6 weeks of study treatment (20 - 60 mg/day group −13.6, placebo group -10.6). The lurasidone 80 - 120 mg/day group (169 patients, -12.6) also demonstrated improvement compared to placebo group (n=171) but the difference was not statistically significant. The result of the ELEVATE study has previously been announced in press releases dated June 9, 2017.

*4 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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