大日本住友製薬

News Release

July 22, 2019
Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Positive Topline Results from a Phase 3 Clinical Study of LONASEN®, an Atypical Antipsychotic Agent, in the Treatment of Adolescent Patients with Schizophrenia in Japan

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura; hereinafter, "Sumitomo Dainippon Pharma") announced today positive topline results from a Phase 3 clinical study in Japan evaluating LONASEN® Tablets (generic name: blonanserin, hereinafter, "LONASEN"), an atypical antipsychotic in the treatment of adolescent patients with schizophrenia met its primary endpoint.

The study was a multi-center, placebo-controlled, randomized, double-blind, 6-week parallel group study intended to evaluate the efficacy and safety of LONASEN and involved 151 adolescent Japanese patients with schizophrenia (age 12 - 18) randomized to three groups receiving dosages of 8 mg/day (n=51), 16 mg/day (n=53), or a placebo (n=47).

For change from baseline to week 6 in the PANSS (Positive and Negative Syndrome Scale) total score (primary endpoint of the study), LONASEN 16 mg/day group (n=52) showed statistically significant improvement compared with the placebo group (n=47) in the FAS (Full Analysis Set) population of 150 subjects (-10.6 in the placebo group and -20.5 in the 16 mg/day group, p=0.012). Meanwhile, the LONASEN 8 mg/day group (n=51) demonstrated improvement over the placebo group but it was not statistically significant (-15.3 in the 8 mg/day group, p=0.230).*

The incidences of adverse events (AEs) observed in the study were 84.3% in the 8 mg/day group, 92.5% in the 16 mg/day group, and 70.2% in the placebo group. AEs observed in LONASEN were generally mild or moderate. The incidences of discontinuation due to AEs were: 9.8% for the 8 mg/day group, 11.3% for the 16 mg/day group, and 6.4% for the placebo group. In the study, LONASEN was well-tolerated.

Based on the results of the study, Sumitomo Dainippon Pharma plans to submit a supplemental new drug application in the first half of fiscal 2020 for approval of an additional indication of LONASEN in the treatment of adolescent patients with schizophrenia in Japan. If approved, LONASEN will be the first atypical antipsychotic agent indicated for adolescents in Japan and is expected to contribute to the treatment of more schizophrenia patients.

* The multiple testing problem in the comparison among the LONASEN 8 mg/day group, 16 mg/day group, and placebo group was adjusted by a closed testing procedure where the testing was conducted in the order of Step 1 and Step 2. Because a significant difference was observed between the LONASEN group, which combined the 8 mg/day group and the 16 mg/day group, and the placebo group (p=0.032) in Step 1, the study moved to Step 2, where the efficacy of the 8 mg/day group and 16 mg/day group was each compared to the efficacy of the placebo group.

<Reference information>

About 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).

About LONASEN

LONASEN is an oral, atypical antipsychotic agent, discovered by Sumitomo Dainippon Pharma, which has been available in Japan since April 2008 for the treatment of schizophrenia. A new drug application for transdermal patch formulation was approved in Japan in June 2019. This drug has an affinity for dopamine D_2/D_3 receptors and serotonin $5\text{-}HT_{2A}$ receptors. In clinical studies, this drug showed efficacy for not only positive symptoms of schizophrenia (such as hallucinations or delusions), but also negative symptoms (such as flat affect or hypobulia).

About schizophrenia

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

According to the 2017 Patient Survey, the total number of patients with “schizophrenia, schizotypal disorder, and delusional disorder” was estimated to be 792,000 in Japan, 1,000 of which were between the ages of 10 and 14 and 7,000 between 15 and 19.

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