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Sumitomo Dainippon Pharma Co., Ltd.
Nitto Denko Corporation

Sumitomo Dainippon Pharma and Nitto Announce Positive Topline Results from Phase 3 Study Evaluating Transdermal Patch Formulation of Atypical Antipsychotic LONASEN®

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Masayo Tada; hereinafter, "Sumitomo Dainippon Pharma") and Nitto Denko Corporation (Head Office: Osaka, Japan, Representative Director, President and CEO: Hideo Takasaki; hereinafter, "Nitto") today announced positive topline results from the Phase 3 study in Japan that evaluated a transdermal patch formulation of an atypical antipsychotic LONASEN® (generic name: blonanserin) (hereinafter, "blonanserin"), which is currently under joint development by the two companies. The study met the primary endpoint and blonanserin was well-tolerated by study participants.

The study was a six-week Phase 3 multi-center, randomized, placebo-controlled, double-blind clinical study intended to evaluate the efficacy and safety of blonanserin and involved 580 adult patients with schizophrenia randomized to three groups receiving dosages of 40 mg/day (n=196), 80 mg/day (n=194), or a placebo (n=190).

For change from baseline to week 6 in the PANSS (Positive and Negative Syndrome Scale) [*1] total score (primary endpoint of the study), both blonanserin 40mg/day and 80 mg/day groups showed statistically significant improvement compared with placebo group in the modified ITT (Intention-to-Treat) population of 577 subjects (difference in score change vs. placebo: 40 mg/day group; -16.4 [adjusted p=0.007], 80 mg/day group; -21.3 [adjusted p<0.001], placebo group; -10.8).

Blonanserin was generally well-tolerated and the adverse events observed in the study, including those related to the skin, were generally mild. The incidence of discontinuation due to adverse events was low (40 mg/day group: 8.7%, 80 mg/day group: 6.2%, placebo group: 8.9%).

Based on the study results, Sumitomo Dainippon Pharma intends to submit an application for manufacturing and marketing approval of blonanserin in Japan during the first half of FY2018.

When treating schizophrenia, medication adherence[*2] is often suboptimal, and this is one of the causes of relapse and rehospitalization.
The superior characteristics of blonanserin include the maintenance of a stable drug concentration in the blood for 24 hours with just once-daily dosing, low susceptibility to dietary effects, allowing patients who have difficulty with oral administration to receive medication, and ease of visual check of medication status.

The two companies expect that blonanserin contributes to improve patients' medication adherence if it becomes a new treatment option for patients with schizophrenia in Japan.

[*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] Medication adherence: The patient's involvement in the decision on treatment regimen and conformance with the agreed-upon regimen

(Reference information)

[About the Phase 3 study]

The study was a six-week Phase 3 multi-center, randomized, placebo-controlled, double-blind clinical trial conducted in Japan and several other countries to evaluate the efficacy and safety of blonanserin in adult patients with schizophrenia. A total of 580 patients were randomized to three groups that received 40 mg/day (n=196), 80 mg/day (n=194), or placebo (n=190). The primary endpoint of the study was change from baseline to week 6 in PANSS total score. A long-term, open-label continuation study is under way to further evaluate the safety and efficacy of blonanserin through 52-week administration of from 40 to 80 mg/day dosages.

【General characteristics of a transdermal patch formulation】

- Capable of maintaining a stable drug concentration in the bloodstream. Also, less susceptible to dietary effects.
- Provides a new therapeutic option to patients who have difficulty with, or who do not prefer oral administration of drugs.
- Dosing can be visually checked.

【Background of Joint Development】

Sumitomo Dainippon Pharma has been engaged in the development of a large number of therapeutic agents. One of the successful examples is LONASEN®, an orally administered product (tablets and powder) for schizophrenia that was first launched in April 2008 in Japan. Nitto has an established technology platform for designing and developing formulations through transdermal therapeutic systems that enable various drugs to be absorbed through the skin into the body. Because dosage forms are an important element that affects medication adherence in the treatment of schizophrenia, uniting their pharmaceutical and formulation technologies, the two companies have been working together since 2010 to develop transdermal patch formulations for the treatment of schizophrenia.

【About LONASEN®】

LONASEN® is an atypical antipsychotic agent with novel structure, discovered by Sumitomo Dainippon Pharma. 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). In Japan it is available from Sumitomo Dainippon Pharma since April 2008 for the treatment of schizophrenia.

【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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