

July 31, 2018

Sumitomo Dainippon Pharma Co., Ltd.
Nitto Denko Corporation

New Drug Application in Japan for Transdermal Patch Formulation of Atypical Antipsychotic LONASEN®

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura hereinafter called “Sumitomo Dainippon Pharma”) announces that it submitted a new drug application in Japan for a transdermal patch formulation of LONASEN® (generic name: blonanserin, hereinafter, “blonanserin”), an atypical antipsychotic agent, which is currently being developed jointly with Nitto Denko Corporation (Head Office: Osaka, Japan, Representative Director, President and CEO: Hideo Takasaki; hereinafter, “Nitto”).

LONASEN® is an oral, atypical antipsychotic agent discovered by Sumitomo Dainippon Pharma, and was launched in Japan for the indication of schizophrenia in April 2008. In order to further stabilize the pharmacokinetics of LONASEN®, since 2010, Sumitomo Dainippon Pharma has been involved in a joint development with Nitto, a company that has the technology required for designing transdermal patch formulations.

Because once-daily application of blonanserin to the skin maintains a stable drug concentration in the blood for 24 hours, high efficacy and safety can be expected. Blonanserin also has the benefits characteristic of patch formulations, namely, it is easy to check medication status visually, and susceptibility to the effects of food is low. This is very helpful to patients for whom oral administration can be problematic, for example, due to difficulty in swallowing.

If blonanserin is approved, the two companies will be able to provide patients affected by schizophrenia with a treatment option that has a novel administration route. This new option is expected to help promote shared decision-making (SDM: approach where patients and healthcare professionals make decisions of therapeutic strategy together), improve medication adherence, and by providing an effective treatment for schizophrenia that a recovery of social function is emphasized.

[Overview of Phase 3 study for blonanserin]

The study was a multi-center, randomized, placebo-controlled, double-blind, phase 3 clinical trial conducted in several countries including Japan, in which a total of 580 adult schizophrenia patients were randomized to three groups that respectively received 40 mg/day (n=196), 80 mg/day (n=194), or placebo (n=190). The study results showed that, regarding the change from baseline at week 6 in the PANSS (Positive and Negative Syndrome Scale) total score (primary endpoint of the study), both the 40 mg/day and 80 mg/day groups showed statistically a significant improvement compared with the placebo group in the modified ITT (Intention-to-Treat) population of 577 subjects. In addition, blonanserin was generally well tolerated, and the adverse events observed in the study, including those related to the skin, were generally mild.

The preliminary results of this study were announced on February 14, 2018.

[LONASEN®]

LONASEN® is an atypical antipsychotic agent with a novel structure, characterized by an affinity for dopamine D₂/D₃ receptors and serotonin 5-HT_{2A} receptors. In clinical studies, this drug showed efficacy for both the positive symptoms (such as hallucinations or delusions) and negative symptoms (such as flat affect or hypobulia) of schizophrenia.

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