

June 18, 2019

Sumitomo Dainippon Pharma Co., Ltd.  
Nitto Denko Corporation

## **Sumitomo Dainippon Pharma and Nitto Denko Announce the Approval of Atypical Antipsychotic LONASEN® Tape in Japan**

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura; hereinafter, “Sumitomo Dainippon Pharma”) announced today that a new drug application for a transdermal patch formulation of atypical antipsychotic LONASEN® Tape 20 mg, 30 mg, and 40 mg (generic name: blonanserin, hereinafter, “this Drug”), which has been developed jointly with Nitto Denko Corporation (Head Office: Osaka, Japan; President & CEO & COO: Hideo Takasaki; hereinafter, “Nitto”), was approved in Japan on June 18, 2019. This Drug is the world’s first transdermal patch formulation of an antipsychotic agent and will be launched by Sumitomo Dainippon Pharma after NHI drug price listing.

LONASEN® Tablet/Powder is an oral antipsychotic agent created by Sumitomo Dainippon Pharma and was launched in Japan for the indication of schizophrenia in April 2008. In order to further stabilize the concentration of blonanserin in blood, Sumitomo Dainippon Pharma has been involved in a joint development since 2010 with Nitto who has the technology required for designing transdermal patch formulations, which led to submission of a new drug application on July 31, 2018.

This Drug is expected to be well-tolerated and efficacious, because once-daily application of this Drug to the skin maintains a stable drug concentration in blood for 24 hours. This Drug also has the beneficial characteristics of patch formulations, namely, it is easy to check medication status and doses, visually. In addition, due to the profile of low food effects, this drug can administer to patients with irregular food take or with difficulty in swallowing.

This approval will allow Sumitomo Dainippon Pharma 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), contribute to the improvement of adherence and treatment of schizophrenia targeting recovery of social function.

### **[About LONASEN®]**

LONASEN® is an atypical antipsychotic agent with affinities for dopamine D<sub>2</sub>/D<sub>3</sub> receptors and serotonin 5-HT<sub>2A</sub> receptors. In clinical studies, it showed efficacy for both the positive symptoms (such as hallucinations or delusions) and negative symptoms (such as blunted affect or avolition) of schizophrenia. Sumitomo Dainippon Pharma currently sells LONASEN® Tablet/Powder and is preparing to launch its transdermal patch formulation.

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