



Dainippon Sumitomo Pharma Co., Ltd

Nitto Denko Corporation

Corporate Communications  
〒541-0045  
2-6-8 Doshomachi, Chuo-ku, Osaka, Japan  
TEL : 06(6203)1407  
FAX : 06(6203)5548  
URL : <http://www.ds-pharma.com/>

Corporate Communications Dept.  
〒530-0001  
2-5-25, Umeda, Kita-ku, Osaka, Japan  
TEL : 06(6452)2215  
FAX : 06(6452)3316  
URL : <http://www.nitto.com/>

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## Dainippon Sumitomo Pharma and Nitto Denko Joint Development Phase 2 studies start on the world's first transdermal patch formulation for schizophrenia treatment

Dainippon Sumitomo Pharma Co., Ltd. (DSP) (Headquarters: Osaka, Japan; President: Masayo Tada) and Nitto Denko Corporation (Nitto Denko) (Headquarters: Osaka, Japan, President: Yukio Nagira) announce they have started Phase 2 studies for a transdermal patch formulation of the atypical antipsychotic LONASEN<sup>®</sup> (generic name: blonanserin), for the transdermal treatment of schizophrenia.

In Phase 1 studies conducted on healthy adults, good transdermal absorption of blonanserin was demonstrated by single and repeated applications of the patch formulation. With these results, both companies started Phase 2 studies to examine the optimal dosing conditions. Working towards the actualization of the world's first transdermal patch formulation for schizophrenia treatment to meet the expectations of patients, families and caregivers, both companies will continue working on the rapid development of this formulation.

### <General characteristics of a transdermal patch formulation>

- Ability to maintain a stable drug concentration in the blood. Also, less susceptible to dietary effects.
- Provides a new treatment option to patients who have difficulty with, or who do not prefer oral administration.
- The medication status can be verified visually.

#### <Background of Joint Development>

DSP has been developing a number of therapeutic agents and in April 2008 launched the oral schizophrenia treatment LONASEN<sup>®</sup> tablets. Nitto Denko has established the technology for a transdermal formulation design through a transdermal therapeutic system that enables various drugs to be absorbed through the skin into the body. Uniting their pharmaceutical and formulation technologies, both companies have continued the development of a transdermal patch formulation for the treatment of schizophrenia since 2010.

#### <About LONASEN<sup>®</sup>>

In clinical studies in Japan, LONASEN<sup>®</sup> showed efficacy on not only positive symptoms of schizophrenia (such as hallucinations and delusions), but also negative symptoms (such as flat affect and hypobulia). This drug also showed a low incidence of adverse reactions such as extrapyramidal symptoms, weight gain or hyperprolactinemia.

#### <About Schizophrenia>

Schizophrenia is a mental illness that affects approximately 800,000 people in Japan. The mesolimbic system and midbrain-cortex dopamine nerves may be associated with the onset of schizophrenia. Various psychiatric symptoms are known to be expressed including positive symptoms such as hallucination/delusion, negative symptoms such as flat emotions/diminished thinking/loss and reduction of volition, and cognitive impairment such as reduced attentiveness/disturbance of information-processing capacity.

#### <Contacts>

Dainippon Sumitomo Pharma Co., Ltd

Corporate Communications

TEL: +81-6-6203-1407

FAX: +81-6-6203-5548

Nitto Denko Corporation

Corporate Communications Dept.

Kazuhito Kouno, Rie Miura

TEL: +81-6-6452-2215

FAX: +81-6-6452-3316

E-mail to: [communication\\_group@nitto.co.jp](mailto:communication_group@nitto.co.jp)