

October 28th, 2013
Dainippon Sumitomo Pharma Co., Ltd.

Application for Marketing Approval Submitted in Taiwan for Atypical Antipsychotic Agent Lurasidone

Osaka, Japan, October 28th, 2013 – Dainippon Sumitomo Pharma Co., Ltd. (“DSP”) (Head Office: Osaka, Japan; President: Masayo Tada) today announced that an application for marketing approval of lurasidone hydrochloride (generic name, “lurasidone”), an atypical antipsychotic agent created by DSP, was submitted on October 25th, 2013 to the Taiwan Food and Drug Administration (TFDA) for the treatment of adult schizophrenia by DSP’s licensee for the product in Taiwan, Standard Chem. & Pharm. Co., Ltd. (“SCP”) (Headquarters: Tainan, Taiwan; CEO: Roy Fan). This marks the first application submission for lurasidone in Asia.

DSP is working to achieve regional expansion of its sales to promote globalization of its business, with a focus on lurasidone and other globally important strategic products. Business development (regulatory approval and marketing) of lurasidone in East Asia and Southeast Asia is a key element in this global strategy.

For Taiwan, a license agreement for the exclusive sales of lurasidone was concluded with SCP in August this year. For the grant of the exclusive license to sell lurasidone in Taiwan, DSP receives an upfront payment from SCP and a milestone fee upon the product approval.

DSP looks forward to working closely with SCP to obtain the approval of lurasidone in Taiwan at the earliest opportunity and to make the new treatment option available to as many patients with schizophrenia as possible.

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[Reference information]

About Standard Chem. & Pharm. Co., Ltd.

SCP is the 4th ranking pharmaceutical company in Taiwan with a broad coverage of therapeutic areas including psychiatry and neurology.

- Company name: STANDARD CHEM. & PHARM. CO., LTD.
- Established: June 1967
- Headquarters: Tainan city, Taiwan
- Representative director: Roy Fan, CEO
- Merged Sales: US\$112 million (2012)
- Employees: 775 (as of October, 2013)

About lurasidone

Lurasidone is an atypical antipsychotic, developed originally by DSP with an affinity for dopamine D2, serotonin 5-HT_{2A} and serotonin 5-HT₇ receptors where it has antagonist effects. In addition, lurasidone is a partial agonist at the serotonin 5-HT_{1A} receptor and has no appreciable affinity for histamine or muscarinic receptors.

The antipsychotic agent is one of DSP's globally important strategic products. It was launched in the United States for the treatment of schizophrenia in February 2011 under the brand name of LATUDA® through DSP's subsidiary Sunovion Pharmaceuticals Inc., and in Canada for the same indication in September 2012. LATUDA® also received the U.S. Food and Drug Administration (FDA) approval for the treatment of bipolar I disorder (bipolar depression) in June 2013.

With respect to Europe, the European Medicines Agency (EMA) accepted in October 2012 the Marketing Authorization Application for lurasidone for the treatment of schizophrenia submitted in the previous month by a European subsidiary of Takeda Pharmaceutical Company, Limited ("Takeda"), DSP's development and commercialization partner for Europe. In Switzerland, Takeda Pharma AG, a wholly owned subsidiary of Takeda, obtained the approval of the Marketing Authorization Application in August 2013.

In Japan, Phase III clinical study is underway for the treatment of schizophrenia by DSP. In addition, Phase III clinical studies for the treatment of bipolar I disorder (bipolar depression) and bipolar maintenance were initiated in September 2013. The application has been filed with the Australian authorities for the treatment of schizophrenia, and obtaining approval in the Chinese and Southeast Asian markets is planned.