DAINIPPON SUMITOMO PHARMA

Takeda

News Release

DSP and Takeda Announce Approval of the Marketing Authorization Application for Atypical Antipsychotic Agent Lurasidone in Switzerland

Osaka, Japan, August 13, 2013 – Dainippon Sumitomo Pharma Co., Ltd. (“DSP”) (Headquarters: Osaka, Japan) and Takeda Pharmaceutical Company Limited (“Takeda”) (Headquarters: Osaka, Japan) today jointly announced that on August 12, Swiss local time, Takeda Pharma AG, a wholly owned subsidiary of Takeda, obtained the approval of the Marketing Authorization Application by Swissmedic for atypical antipsychotic medication lurasidone hydrochloride ("lurasidone") for the treatment of patients with schizophrenia.

Lurasidone, orally administrated once daily, is an atypical antipsychotic medication discovered and developed by DSP. In the U.S., it was approved for the treatment of schizophrenia and also for major depressive episodes associated with bipolar I disorder in October 2010 and June 2013, respectively. It is being marketed as LATUDA® in the U.S. and Canada by Sunovion Pharmaceuticals Inc., a wholly owned subsidiary of DSP. In March 2011, DSP and Takeda signed a license agreement for lurasidone for the joint development and exclusive commercialization by Takeda in the 26 member states of the European Union at that time excluding the United Kingdom, Switzerland, Norway, Turkey and Russia.

The Marketing Authorization Application was submitted in Switzerland in March 2012 based on the dossier used for submissions and subsequent approvals by the U.S. Food and Drug Administration and Health Canada. In the European Union, the Marketing Authorization Application was accepted for review by the European Medicines Agency in October 2012 and is currently under review.

DSP will work to grow lurasidone as its global strategic product, to maximize product value by expanding business regions in its third Mid-term Business Plan covering the period up to fiscal 2017.

Takeda believes that lurasidone will be an important driver for accelerating the exploration of its specialty care business in Europe as part of its Mid-Range Growth Strategy announced in May 2013.

According to the World Health Organization, schizophrenia is a severe form of mental illness affecting about seven of every one thousand adults, mostly in the age group 15-35 years, and it affects about 24 million people worldwide.* Both DSP and Takeda are committed to responding to the unmet medical needs of patients with schizophrenia through providing lurasidone to those who need it. This approval by Swissmedic is an important milestone as the first approval of lurasidone in Europe.

*http://www.who.int/mental_health/management/schizophrenia/en/

About lurasidone

Lurasidone is an atypical antipsychotic, developed originally by DSP with an affinity for dopamine D2, serotonin 5-HT2A and serotonin 5-HT7 receptors where it has antagonist effects. In addition, lurasidone is a partial agonist at the serotonin 5-HT1A receptor and has no appreciable affinity for histamine or muscarinic receptors.

Lurasidone (brand name LATUDA®) was approved for the treatment of schizophrenia by the United States Food and Drug Administration in October 2010 and by Health Canada in June 2012. LATUDA® was launched in the United States for the treatment of schizophrenia in adults in February, 2011 (US time) and in Canada in September, 2011 (Canada Time) through DSP's subsidiary Sunovion Pharmaceuticals Inc. LATUDA® received an FDA approval also for the treatment of bipolar I disorder (bipolar depression) in June 2013.

In Japan Phase III clinical study is underway for the treatment of schizophrenia by DSP. In addition, preparations are underway for Phase III clinical study for the treatment of bipolar I disorder (bipolar depression). The application has been filed with the Australian authorities for the treatment of schizophrenia, and development in the Chinese and Southeast Asian markets is planned.

About Dainippon Sumitomo Pharma Co., Ltd.

Dainippon Sumitomo Pharma Co., Ltd., defines its corporate mission as "to broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives for people worldwide". By pouring all our efforts into the research and development of new drugs, we aim to provide innovative and effective pharmaceutical solutions to people not only in Japan but also around the world in order to realize our corporate mission. Additional information about DSP is available through its corporate website, www.ds-pharma.com.

About Takeda Pharmaceutical Company Limited

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, www.takeda.com.

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