DAINIPPON SUMITOMO PHARMA

Takeda

News Release

DSP and Takeda Announce the Acceptance of the European Medicines Agency Submission of an Atypical Antipsychotic Agent Lurasidone

Osaka, Japan, October 25, 2012 – Dainippon Sumitomo Pharma Co., Ltd. ("DSP") (Headquarters: Osaka, Japan) and Takeda Pharmaceutical Company Limited ("Takeda") (Headquarters: Osaka, Japan) today announced that the European Medicines Agency (EMA) has confirmed the acceptance for review of the Marketing Authorization Application (MAA) for an atypical antipsychotic medication lurasidone hydrochloride for the treatment of schizophrenia. The MAA was filed by Takeda Global Research & Development Centre (Europe).

Lurasidone, orally administrated once daily, is an atypical antipsychotic medication discovered and developed by DSP with a unique chemical structure as compared to other existing antipsychotic medicines. Takeda entered into a license agreement with DSP stipulating the joint development and grant of an exclusive commercialization right of the product to Takeda in 26 member states of the European Union (excluding the United Kingdom), and Switzerland, Norway, Turkey and Russia in March 2011.

The MAA submission is based on the data from more than 50 clinical trials involving more than 3,800 lurasidone-treated subjects. In phase 3 clinical trials, in which the efficacy and safety of lurasidone in the treatment of patients with schizophrenia were evaluated, lurasidone demonstrated significantly greater improvement versus placebo in the primary efficacy endpoint [Positive and Negative Syndrome Scale (PANSS)* total score]. The most commonly observed adverse reactions in patients treated with lurasidone were somnolence, akathisia, nausea and parkinsonism. Clinical trials also demonstrated that lurasidone was well-tolerated with minimal impact on weight or metabolic parameters.

"Lurasidone the DSP Group's core product for overseas expansion, and I am very pleased that we have achieved the important milestone of submitting an MAA in Europe." said Masayo Tada, President and Chief Executive Officer of DSP. "Through the cooperation between our two companies, we are aiming for the swiftest approval in order to provide this drug to more patients as soon as possible."

"We are very pleased with the submission of lurasidone in the E.U.," said Yasuchika Hasegawa, president & CEO of Takeda. "We believe the submission will lead to the enhancement of our central nervous system franchise, one of our core therapeutic areas. Once approved, we believe we can contribute to the treatment of patients with schizophrenia."

* A medical scale used for mainly measuring symptom severity of patients with schizophrenia. It consists of 30 items---7 items of positive scale, 7 items of negative scale and 16 items of general psychopathology scale. Each item is rated from 1 (absent) to 7 (extreme).

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 on 28 October 2010 and by Health Canada on 13 June 2012. LATUDA was launched in the United States for the treatment of schizophrenia in adults on February 4, 2011 (US time) and in Canada on September 17, 2011 (Canada Time) through DSP's subsidiary Sunovion Pharmaceuticals Inc.

In the U.S. and Canada, the recommended starting dose for LATUDA is 40mg/day taken with food (at least 350 calories) with no initial dose titration required. The maximum recommended dose is 160 mg/day. The efficacy of lurasidone for the treatment of schizophrenia was established in five, short-term (6-week), placebo-controlled clinical studies in adult patients who met DSM-IV criteria for schizophrenia. In these studies, lurasidone demonstrated significantly greater improvement versus placebo on the primary efficacy measures [the Positive and Negative Syndrome Scale (PANSS) total score and the Brief Psychiatric Rating Scale-derived from PANSS (BPRSd)] at study endpoint. Clinical trials contributed to the understanding of the tolerability and safety profile of lurasidone. The most commonly observed adverse reactions (≥5% and at least twice that for placebo) in patients treated with lurasidone in short-term clinical studies were somnolence, akathisia, nausea and parkinsonism. Efficacy and safety of lurasidone were also demonstrated in long-term studies.

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 patients worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, www.takeda.com.

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