News Release

Dainippon Sumitomo Pharma and Takeda Announce the European Marketing Authorization for Latuda® (lurasidone) - a New Atypical Antipsychotic Medication for Adults with Schizophrenia

Osaka, Japan, March 31, 2014 – Dainippon Sumitomo Pharma Co., Ltd. ("DSP") (Head Office: Osaka, Japan) and Takeda Pharmaceutical Company Limited ("Takeda") (Head Office: Osaka, Japan) today jointly announced that the European Commission has granted Marketing Authorization for once-daily oral Latuda® (lurasidone) for the treatment of schizophrenia in adults. The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a Positive Opinion for Latuda on January 23, 2014.

About 3.5 million people in Europe are currently living with schizophrenia which can have a huge impact on those affected, their families and caregivers.[1] Symptoms can be diverse and include hallucinations, distorted reality, depression and social withdrawal. Schizophrenia is also associated with shortened life expectancy of 10-22.5 years,[2,3] which can in part be due to the undesirable effects of antipsychotics such as weight gain, increased blood pressure and increased blood sugar.[4,5] The leading cause of mortality for people with schizophrenia is cardiovascular disease[5] – an estimated 75% die from this versus a general population mortality rate of 50%.[6]

Prof. Hans-Jürgen Möller, Direktor der Uni-Psychiatrie München said, *"We know that many people living with schizophrenia struggle to remain on treatment due in part to the side effects associated with currently available therapies. Today's announcement means that physicians within the European Union will have access to a new treatment to help eligible patients manage their disease. Flexible treatments that are convenient for patients and that can help to control the numerous and complex factors associated with schizophrenia, may be of value to patients, as well as their families and caregivers."*

The Marketing Authorization was based on a comprehensive clinical trial program of eight positive studies, which included placebo and active comparators. The review also contained more than 50 clinical trials and more than 4,500 lurasidone-treated subjects. Lurasidone was shown to be effective in treating both positive and negative symptoms in acutely psychotic patients with schizophrenia.[7,8,9,10,11] In short and long term clinical studies, lurasidone has demonstrated effectiveness with low rates of metabolic change.[9,10,12] It is important to minimize the adverse effect of treatments on long-term physical health as patients are likely to remain on therapy for many years.[5]

Lurasidone demonstrated a statistically significant separation from placebo seen as early as day four on primary efficacy measures in some of the pivotal trials in schizophrenia.[7] The most frequent adverse reactions seen in short-term clinical studies (incidence ≥ 5% and at least twice as frequent as with placebo) were somnolence, akathisia, nausea, parkinsonism and dystonia.[13]

Clinical studies have shown that lurasidone was generally well-tolerated and had low rates of weight increase, as well as lipid and glucose disturbance, in the treatment of patients with schizophrenia.[14,15,16,17]

Lurasidone demonstrated significant reductions in mean weight and BMI over 12 months in contrast to increases in risperidone-treated patients.[12] In separate studies, lurasidone demonstrated significant reduction in clinically significant weight gain (≥ 7%) compared to quetiapine XR over 12 months[18], and patients switching from olanzapine to lurasidone experienced mean weight loss during the subsequent 6 months.[19]

"Lurasidone is the DSP Group's core product for global expansion, and I am very pleased that we have achieved the important milestone of the approval of lurasidone for schizophrenia in Europe," said Masayo Tada, President and Chief Executive Officer of DSP. *"We intend to build upon the success lurasidone has shown in the United States and through the partnership with Takeda to ensure we provide this new treatment option to patients across Europe."*

"We are very pleased with the marketing authorization of lurasidone in the European Union," said Yasuchika Hasegawa, president & CEO of Takeda. *"We believe lurasidone represents an important new treatment option for people in Europe living with schizophrenia. This milestone also enhances our central nervous system franchise, one of our core therapeutic areas."*

Latuda will be marketed in the UK by Sunovion Pharmaceuticals Europe Ltd., a subsidiary of DSP, and across Europe by Takeda subsidiaries.

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About Latuda® (lurasidone)
Latuda is an atypical antipsychotic, developed originally by Dainippon Sumitomo Pharma Co., Ltd. ("DSP") with a high affinity for dopamine D_2, serotonin 5-HT_{2A} and serotonin 5-HT_7 receptors where it has antagonistic effects. In addition, Latuda is a partial agonist at the serotonin 5-HT_{1A} receptor and has no appreciable affinity for histamine or muscarinic receptors. Latuda was approved for the treatment of schizophrenia in adults by the United States Food and Drug Administration in October 2010, by Health Canada in June 2012, and by the Swiss Agency for Therapeutic Products in August 2013. Lurasidone was launched as Latuda® for the treatment of schizophrenia in adults in the United States in February 2011 and in Canada in September 2012 through DSP's subsidiary Sunovion Pharmaceuticals Inc., and in Switzerland in September 2013 through Takeda. In Japan a Phase III clinical study is underway for the treatment of schizophrenia by DSP. Furthermore, we plan to launch the product in Australia, Taiwan, China and Southeast Asia.

About schizophrenia
Schizophrenia is a severe chronic mental condition which can affect both men and women. Patients with schizophrenia have a life span that is decreased by approximately 10–22.5 years compared with the general population.[2,3,20,21]

Antipsychotic pharmacotherapy is the cornerstone of treatment for patients with schizophrenia, with agents generally classed as typical or atypical. Atypical agents are broadly considered to have tolerability benefits over typical agents.[22] Switching antipsychotic medication is common in the treatment of patients with schizophrenia either due to residual or emergent symptoms, adverse events or tolerability issues.[23,24]

Direct and indirect costs associated with caring for patients with schizophrenia are considerable and can include utilization of other health services, pharmacotherapy, community care, supportive therapy, informal care and private expenditures, and patient and caregiver lost productivity.[25,26] Hospitalization associated with patient relapse can significantly increase costs associated with disease management in schizophrenia.[27]

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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