

# News Release

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## **Dainippon Sumitomo Pharma and Takeda Receive Positive CHMP Opinion for Lurasidone - a New Atypical Antipsychotic Medication for Adults with Schizophrenia**

**Osaka, Japan, January 27, 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 Committee for Medicinal Products for Human Use (CHMP), of the European Medicines Agency (EMA), has issued a Positive Opinion for lurasidone for the treatment of schizophrenia in adults. Lurasidone is a once-daily oral treatment that is currently available in Switzerland, the United States and Canada having been approved for use by the respective regulatory authorities.

The Positive CHMP Opinion was based on a comprehensive clinical trial program which included placebo and active comparators. Lurasidone was shown to be effective in treating both positive and negative symptoms in acutely psychotic patients with schizophrenia over 6 weeks.<sup>1,2,3,4,5</sup> In short and longer term clinical studies, lurasidone has demonstrated effectiveness with low rates of metabolic change.<sup>1,2,6</sup> 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.

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. The most frequent adverse reactions seen in short-term clinical studies (incidence  $\geq$  5% and at least twice as frequent as with placebo) were somnolence, akathisia, nausea, Parkinsonism and dystonia.<sup>7</sup>

*"As a practicing psychiatrist, I am interested in new, effective agents for the treatment of severely ill patients with mental disorders. We need effective, well-tolerated and metabolically neutral treatment alternatives. Lurasidone has an interesting profile, which could benefit many patients with schizophrenia"* says Philipp Eich MD, Klinik für Psychiatrie und Psychotherapie, Liestal, Switzerland.

Data for lurasidone was presented at last year's European College of Neuropsychopharmacology (ECNP) Congress showing lurasidone to have a favourable metabolic side effect profile<sup>8,9,10,11</sup> and to be a well-tolerated, efficacious option for patients with schizophrenia switching medication.<sup>11</sup>

### **About Lurasidone**

Lurasidone is an atypical antipsychotic, developed originally by Dainippon Sumitomo Pharma Co., Ltd. ("DSP") with a high affinity for dopamine D<sub>2</sub>, serotonin 5-HT<sub>2A</sub> and serotonin 5-HT<sub>7</sub> receptors where it has antagonistic effects. In addition, lurasidone is a partial agonist at the serotonin 5-HT<sub>1A</sub> receptor and has no appreciable affinity for histamine or muscarinic receptors. Lurasidone was approved for the treatment of schizophrenia 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<sup>®</sup> 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. An application has been filed with the Australian Therapeutic Goods Administration for the treatment of patients with schizophrenia, as well as the Taiwan Food and Drug Administration (TFDA) and further development in the Chinese and Southeast Asian markets is planned.

### **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.<sup>12,13,14,15</sup>

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.<sup>16</sup> Switching antipsychotic medication is common in the treatment of patients with schizophrenia either due to residual or emergent symptoms, adverse events or tolerability issues.<sup>17,18</sup>

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.<sup>19,20</sup> Hospitalization associated with patient relapse can significantly increase costs associated with disease management in schizophrenia.<sup>21</sup>

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### **About Dainippon Sumitomo Pharma Co., Ltd.**

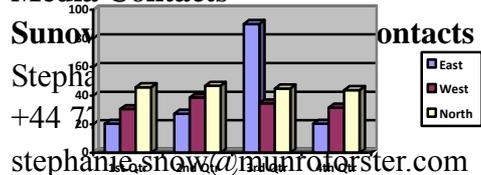
Dainippon Sumitomo Pharma Co., Ltd., defines its corporate mission as “to broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives for people worldwide”. By pouring all our efforts into the research 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](http://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](http://www.takeda.com).

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