

News Release

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DSPE Regulatory Update: Acceptance of the European Medicines Agency Submission for an Atypical Antipsychotic Agent Lurasidone

London, UK, October 25, 2012 –Dainippon Sumitomo Pharma Europe Ltd (“DSPE”) (Headquarters: London, UK) today announced that the European Medicines Agency (EMA) has confirmed that the Marketing Authorisation Application (MAA) for lurasidone hydrochloride, an atypical antipsychotic investigational medicine for the treatment of schizophrenia, is valid.

The MAA was filed by Takeda Global Research & Development Centre (Europe). Dainippon Sumitomo Pharma Co., Ltd (“DSP”) discovered and developed lurasidone. Takeda entered into a license agreement with DSP stipulating the joint development and granting of an exclusive commercialisation 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. DSPE will be undertaking the commercialisation of lurasidone in the UK.

The MAA submission is based on data from more than 50 clinical trials involving more than 3,800 subjects. Phase 3 clinical trials, demonstrated significantly greater improvement in the primary efficacy endpoint [Positive and Negative Syndrome Scale (PANSS)]* total score in patients with schizophrenia treated with lurasidone administered once daily versus placebo. The most commonly observed adverse reactions in patients treated with lurasidone were somnolence, akathisia, nausea and parkinsonism. Lurasidone was generally well-tolerated with minimal effect on weight or metabolic parameters.

“Lurasidone is anticipated to be a core product for the expansion of the DSP Group, 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 Dainippon Sumitomo Pharma Co., Ltd. “Through the cooperation between our companies, we are working towards a swift approval in order to make this investigational medicine available as soon as possible.”

* 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. Lurasidone is a partial

agonist at the serotonin 5-HT_{1A} 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, 2012 (Canada Time) through DSP's subsidiary Sunovion Pharmaceuticals Inc.

About Dainippon Sumitomo Pharma Europe Ltd.

Dainippon Sumitomo Pharma Europe Ltd. (DSPE) is a subsidiary of Dainippon Sumitomo Pharma Co., Ltd. (DSP) which 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”. Lurasidone represents a significant step in positioning DSP as an internationally recognised global pharmaceutical company. DSP has the commercialisation rights to lurasidone in the UK and DSPE has been an established subsidiary hitherto focused on clinical development activities. DSP is now broadening capabilities in the UK subsidiary by creating a commercial organisation in DSPE to support the future launch of lurasidone.

Additional information about DSP is available through its corporate website, www.ds-pharma.com.

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