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Dainippon Sumitomo Pharma Co., Ltd.

Dainippon Sumitomo Pharma Submits Marketing Authorization Application in Australia for Atypical Antipsychotic Agent Lurasidone

Osaka, Japan, April 15, 2013 – Dainippon Sumitomo Pharma Co., Ltd. (DSP) (Headquarters: Osaka, Japan; President: Masayo Tada) announces that the Australian Therapeutic Goods Administration (TGA) has confirmed the acceptance of a marketing authorization application for lurasidone hydrochloride (generic name) for the treatment of schizophrenia in adults. This marketing authorization application was submitted to the TGA in March 2013.

DSP has positioned lurasidone as a product that plays a central role in the DSP Group's overseas expansion. DSP's US subsidiary Sunovion Pharmaceuticals Inc. launched lurasidone under the brand name "LATUDA[®]" in February 2011 in the US, and in Canada in September 2012.

In Europe, DSP has been developing lurasidone in collaboration with Takeda Pharmaceutical Company Limited. In September 2012 Takeda submitted a Marketing Authorization Application (MAA) for lurasidone to the European Medicines Agency (EMA) for the treatment of schizophrenia, and in October 2012 the EMA confirmed acceptance of the MAA for review.

In Japan, DSP conducts Phase 3 clinical trials.

DSP is aiming for the swiftest approval possible in Australia in order to provide this drug to more patients, further contributing to the treatment of schizophrenia.

(Reference)

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.

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