Sumitomo Dainippon Pharma

News Release

January 29, 2019

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces the Approval of Atypical Antipsychotic Latuda® (lurasidone HCl) for the Treatment of Patients with Schizophrenia in China

Sumitomo Dainippon Pharma Co., Ltd. (Head office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced today that the National Medical Products Administration (NMPA) granted the import drug license for Latuda®, an atypical antipsychotic (generic name: lurasidone hydrochloride), for the treatment of patients with schizophrenia on January 24, 2019. The import drug license application was submitted in December 2015.

Sumitomo Pharmaceuticals (Suzhou) Co., Ltd., wholly-owned subsidiary of Sumitomo Dainippon Pharma in China plans to launch LATUDA in China in FY2019 after the necessary procedures are implemented.

Through the approval in China for LATUDA, Sumitomo Dainippon Pharma expects to make a contribution to the treatment of patients with schizophrenia in China by offering LATUDA as a new treatment option.

(Reference)

About lurasidone

Lurasidone is an atypical antipsychotic agent that is believed to have an affinity for dopamine D_2, serotonin 5-HT_{2A} and serotonin 5-HT_7 receptors where it has antagonist effects. In addition, LATUDA is a partial agonist at the serotonin 5-HT_{1A} receptor and has no appreciable affinity for histamine H_1 or muscarinic M_1 receptors.

Lurasidone was approved for the treatment of schizophrenia in the United States in 2010, in Canada in 2012, in Switzerland in 2013, in Europe and Australia in 2014, in Taiwan, Russia, Singapore, Thailand and Hong Kong in 2016, and in Brazil and UAE in 2017, and also was approved for the treatment of bipolar I depression in the United States in 2013, in Canada in 2014, in Russia, Brazil and Taiwan in 2017. Sumitomo Dainippon Pharma is aiming to submit new drug applications for approval of the treatment of schizophrenia and bipolar depression in Japan during the first half of FY2019.

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