
Press Release

March 30, 2026

Sumitomo Pharma Co., Ltd.

Sumitomo Pharma Submits Partial Change Application in Japan to Add Pediatric Dosage and Administration for LATUDA® in Schizophrenia

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Toru Kimura; the “Company”) today announced that the Company has submitted a partial change application in Japan to add pediatric dosage and administration for LATUDA® Tablets (generic name: lurasidone hydrochloride; the “Product”), an atypical antipsychotic agent, for the treatment of schizophrenia.

This application is based on results from a Phase 3 study conducted in pediatric patients with schizophrenia in Japan.

In Japan, the number of pediatric patients with schizophrenia is estimated to be approximately 6,000 to 7,000 (0.7–0.8% of the adult patient population). Early and continuous treatment from the time of onset is considered important. With approval of pediatric dosage and administration supported by clinical evidence in Japanese patients, the Company expects to provide a new treatment option that ensures continuity of care from childhood to adulthood, thereby contributing to the treatment of pediatric schizophrenia.

(Reference)

About LATUDA®

LATUDA® is an atypical antipsychotic agent with an original chemical structure created by Sumitomo Pharma, acting as an antagonist at dopamine D₂, serotonin 5-HT_{2A}, and serotonin 5-HT₇ receptors, and as a partial agonist at serotonin 5-HT_{1A} receptors, while exhibiting no appreciable affinity for histamine H₁ or muscarinic M₁ receptors. Based on this receptor profile, the Product was developed with the expectation of achieving strong efficacy and favorable tolerability in improving a broad range of psychiatric symptoms, including positive and negative symptoms of schizophrenia, as well as depressive episodes associated with bipolar disorder.

In Japan, the Product is approved for the treatment of schizophrenia and for the improvement of depressive episodes associated with bipolar disorder in adults. Outside Japan, including in the U.S., the Product is approved as a treatment for schizophrenia in 54 countries and regions, and as a treatment for depressive episodes associated with bipolar I disorder in 21 countries and regions.

About Schizophrenia

Approximately 800,000 people in Japan are affected by schizophrenia, a chronic disorder with a high rate of recurrence. A wide range of symptoms may emerge over time, making daily life, education, and employment difficult. These symptoms include positive symptoms such as hallucinations, delusions, and disorganized thinking; negative symptoms such as emotional

flattening, social withdrawal, and reduced spontaneity; cognitive impairments such as diminished memory, attention, and executive function; as well as anxiety and depression.

Pharmacological treatment is the foundation of therapy, with atypical antipsychotic agents playing a central role. However, several challenges remain, including insufficient efficacy across diverse psychiatric symptoms and the occurrence of metabolism-related adverse events, such as weight gain and abnormalities in glucose and lipid metabolism.

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