

June 4 2020

Sumitomo Dainippon Pharma Co., Ltd.

**Sumitomo Dainippon Pharma Announces Launch of
Atypical Antipsychotic Agent, LATUDA® Tablets in Japan**

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced today the launch of LATUDA® Tablets 20 mg, 40 mg, 60 mg and 80 mg (generic name: lurasidone hydrochloride, hereinafter, “this Drug”), an atypical antipsychotic agent for schizophrenia and bipolar depression, in Japan on June 11.

This Drug is an atypical antipsychotic agent with an original chemical structure created by Sumitomo Dainippon Pharma that has antagonistic effects for dopamine D₂, serotonin 5-HT_{2A} and serotonin 5-HT₇ receptors. It is also a partial agonist for serotonin 5-HT_{1A} receptors but has no appreciable affinity for histamine H₁ or muscarinic M₁ receptors. Based on this receptor profile, this Drug should be excellent in relieving various psychiatric symptoms of schizophrenia, such as positive and negative symptoms, and bipolar depression symptoms. It is also expected to have high tolerability and could become a medication of first choice for the treatment of both diseases.

Outside Japan, as of May 2020, this Drug had been approved as a treatment for schizophrenia in 47 countries and regions, including European countries and the US, and for depressive episodes associated with bipolar 1 disorder in 7 countries and regions including the US. Also, from the viewpoint of tolerability and treatment continuation, this Drug is recommended in the latest treatment guidelines in other countries in consideration of low incidence of metabolism-related adverse events, such as weight gain and glucose metabolism disorders. It is also recommended as a drug of first choice for bipolar depression.

By providing a new treatment option with the launch of this Drug, Sumitomo Dainippon Pharma hopes to contribute to the further development of treatment for schizophrenia and bipolar depression as well as the health of patients and their families, and enable them to live more fulfilled lives.

References

About LATUDA®

The safety and efficacy of LATUDA® were confirmed in multinational Phase 3 studies in schizophrenia patients (PASTEL study, JEWEL study) and a long-term extension study (JEWEL extension study) as well as in a multinational phase 3 study in bipolar 1 depression patients (ELEVATE Trial). It was approved in Japan in March 2020. For the detailed results of each trial, please refer to the press release dated March 25, 2020 entitled “Sumitomo Dainippon Pharma Announces Approval of Atypical Antipsychotic Agent, LATUDA® Tablets in Japan” (<https://www.ds-pharma.com/ir/news/2020/20200325-1.html>)

About schizophrenia

Around 800,000 people in Japan suffer from schizophrenia, a chronic disease with a high recurrence rate. It has been reported that various symptoms appear as time passes, making daily living as well as going to school or work difficult. They include positive symptoms such as hallucinations, delusions and thought disorders; negative symptoms such as emotional flattening, social withdrawal and decreased spontaneity; cognitive impairment symptoms such as reduced memory, attention and ability to execute tasks; and anxiety and depression. It is basically treated with drugs, with atypical antipsychotic agents playing a central role. However, various treatment issues remain to be solved, among them insufficient efficacy against various psychiatric symptoms and metabolism-related adverse events such as weight gain, glucose metabolism and lipid metabolism disorders.

About bipolar depression

In Japan, there are considered to be around 220,000 people with bipolar disorder, a serious chronic disease in which a manic state and a depressive state alternate. For many patients, it has been found that the period of the depressive state is longer than that of the manic state and the frequent recurrence of the depressive state will be a major obstacle in participating in society as well as in family life. Drug therapy is the basic form of treatment. However, while there are many effective treatments for manic symptoms at present, therapy options for depressive symptoms are limited, which is considered to be an important issue in the treatment of bipolar disorder.

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