Sunovion Receives FDA Approval of Supplemental New Drug Application (sNDA) for Use of Latuda® (lurasidone HCl) in the Treatment of Bipolar Depression in Pediatric Patients (10 to 17 Years of Age)

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MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc. (Sunovion) today announced that the U.S. Food and Drug Administration (FDA) approved a supplemental New Drug Application (sNDA) that expands the use of Latuda® (lurasidone HCl) to include the treatment of major depressive episode associated with bipolar disorder (bipolar depression) in pediatric patients (10 to 17 years of age).

Latuda® is also approved in the U.S. for the treatment of adults with bipolar depression as monotherapy and adjunctive therapy with lithium or valproate, and for the treatment of adolescents (13 to 17 years of age) and adults with schizophrenia.

**Bipolar disorder** is a leading cause of disease burden in the pediatric population both here in the U.S. and across the globe, but unfortunately, few treatments are effective in treating young people living with the condition, said Robert Findling, M.D., M.B.A., Vice President of Pediatric Psychiatric Services and Research at the Kennedy Krieger Institute, Director, Child & Adolescent Psychiatry at the Johns Hopkins University School of Medicine. “We know that children who have been diagnosed with bipolar disorder can be at risk for poor school performance and impairments in social functioning. The FDA approval of this medicine for the treatment of pediatric patients with bipolar disorder is significant for several reasons. First, it is a new treatment option for this vulnerable group of young people. Also, it is the first single-agent formulation to receive regulatory approval for this pediatric indication.”

The approval for the expanded indication of Latuda® was supported by data from a Phase 3 clinical study of children and adolescents (10 to 17 years of age) with bipolar depression. In this study, LATUDA was associated with statistically significant and clinically meaningful improvement in bipolar depression symptoms compared to placebo and was generally well-tolerated.

“With limited approved treatment options for these patients, the FDA approval of LATUDA marks an important milestone for the mental health community,” said David Frawley, Executive Vice President, Chief Commercial Officer at Sunovion. “We are proud to build on the strong foundation of LATUDA for adults with bipolar depression and to now be able to offer this medicine as a treatment option for pediatric patients living with this devastating condition.”

Anyone seeking medical information, patient assistance or other information can access Sunovion Answers at LATUDA.com/answers or by calling 1-855-552-8832 Sunday through Saturday from 8:00 a.m. to midnight ET.

**Phase 3 Study Results**

In the six-week, randomized, double-blind, placebo-controlled study, 347 children and adolescents (10 to 17 years of age) with bipolar depression received once-daily LATUDA flexibly dosed (20-80 mg/day) or placebo. LATUDA was associated with statistically significant and clinically meaningful improvement in bipolar depression symptoms compared to placebo, based on the primary efficacy endpoint of change from baseline to Week 6 on the Children’s Depression Rating Scale, Revised (CDRS-R) total score (-21.0 vs. -15.3; effect size = 0.45, p<0.0001). Statistically significant and clinically relevant change from baseline to Week 6 on the Clinical Global Impression-Bipolar Version, Severity of Illness (CGI-BP-S) score (depression) at the secondary endpoint was also seen with LATUDA compared to placebo (-1.49 vs. -1.05; effect size = 0.44, p<0.001).

LATUDA was generally well-tolerated. The most common treatment-emergent adverse events (TEAEs) reported for LATUDA compared to placebo were nausea (16.0% vs. 5.8%), weight gain (6.9% vs. 1.7%) and insomnia (5.1% vs. 2.3%).

**About Bipolar Disorder**

Bipolar disorder is a chronic mental health condition that can affect individuals of all ages and is characterized by potentially debilitating mood swings, including periods of depression and mania. It affects approximately 12.6 million adults in the U.S. 

Approximately 50 to 66 percent of adults with bipolar disorder experience their first symptoms before age 18, and it can be difficult to diagnose. Bipolar disorder affects approximately 1.7 percent of the pediatric population in the U.S.

Bipolar disorder is the fourth leading cause of disease burden among children and adolescents worldwide. Bipolar disorder is characterized by at least one lifetime manic or mixed episode; individuals often have one or more depressive episodes. Bipolar depression refers to the depressive phase of bipolar disorder.

Its symptoms include: depressed mood, loss of interest or pleasure in activities, significant weight loss, insomnia, fatigue, feelings of worthlessness, diminished ability to concentrate and recurrent thoughts of death or suicide attempt. When symptomatic, depressive symptoms affect patients more commonly than manic symptoms. Bipolar disorder has been shown to result in significant impairment in work, family and social function, and is associated with increased direct and indirect health care costs.

**About LATUDA**

LATUDA is a prescription medicine used:

- To treat adults and adolescents (13 to 17 years of age) with schizophrenia
- Alone to treat adults, children and teenagers (10 to 17 years of age) with depressive episodes that happen with bipolar disorder (bipolar depression)
- With the medicine lithium or valproate to treat adults with depressive episodes that happen with bipolar disorder (bipolar depression)

LATUDA is available in five tablet strengths: 20 mg, 40 mg, 60 mg, 80 mg and 120 mg.

The effectiveness of LATUDA for longer-term use, that is, for more than one year, is not known. Clinical practice guidelines recommend that the current treatment should be periodically re-evaluated to determine both the necessity and the usefulness of the drug for each individual patient.

LATUDA is available in five tablet strengths: 20 mg, 40 mg, 60 mg, 80 mg and 120 mg.

**IMPORTANT SAFETY INFORMATION FOR LATUDA**

**INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; AND SUICIDAL THOUGHTS AND BEHAVIORS**

Increased risk of death in elderly people with dementia-related psychosis. Medicines like LATUDA can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). LATUDA is not approved for the treatment of people with dementia-related psychosis.

Antidepressant medicines may increase suicidal thoughts or behaviors in some children, teenagers, and young adults within the first few months of treatment and when the dose is increased. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Patients with or at risk for antidepressant medicines may increase suicidal thoughts or behaviors, including thinking about suicide and attempting suicide. Even though antidepressant medicines are prescribed in an effort to treat depression and other severe medical illnesses, patients are advised to discuss all treatment options with their doctor. LATUDA should be used cautiously in the elderly with dementia-related psychosis that can lead to death.

LATUDA may cause serious side effects, including:

- Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death
- Neuroleptic malignant syndrome (NMS) is a serious condition that can lead to death. Call your health care provider or go to the nearest hospital emergency room right away if you have any of the following signs and symptoms of NMS: high fever, increased sweating, stiff muscles, confusion, or changes in your breathing, heart rate, and blood pressure
- Uncontrolled body movements (tardive dyskinesia). LATUDA may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away even if you stop taking LATUDA. Tardive dyskinesia may also start after you stop taking LATUDA
- Problems with your metabolism such as:
High blood sugar (hyperglycemia) and diabetes: Increases in blood sugar can happen in some people who take LATUDA. Extremely high blood sugar can lead to coma or death. If you have diabetes or risk factors for diabetes (such as being overweight or a family history of diabetes), your health care provider should check your blood sugar before you start and during treatment with LATUDA.

Call your health care provider if you have any of these symptoms of high blood sugar (hyperglycemia) while taking LATUDA: FEEL very thirsty, need to urinate more than usual, feel very hungry, feel weak or tired, feel sick to your stomach, feel confused, or your breath smells fruity.

Increased fat levels (cholesterol and triglycerides) in your blood

Weight gain. You and your health care provider should check your weight regularly during treatment with LATUDA.

Increased prolactin levels in your blood (hyperprolactinemia). Your health care provider may do blood tests to check your prolactin levels during treatment with LATUDA. Tell your health care provider if you have any of the following signs and symptoms of hyperprolactinemia:

- Females: absence of your menstrual cycle or secretion of breast milk when you are not breastfeeding
- Males: problems getting or maintaining an erection (erectile dysfunction) or enlargement of breasts (gynecomastia)

Low white blood cell count. Your health care provider may do blood tests during the first few months of treatment with LATUDA.

Decreased blood pressure (orthostatic hypotension). You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.

Falls. LATUDA may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position (orthostatic hypotension), and can slow your thinking and motor skills, which may increase the risk of falling or other injuries.

Seizures (convulsions).

Problems controlling your body temperature so that you feel too warm. Do not become too hot or dehydrated during treatment with LATUDA. Do not exercise too much. In hot weather, stay inside in a cool place if possible. Stay out of the sun. Do not wear too much clothing or heavy clothing. Drink plenty of water.

Mania or hypomania (manic episodes) in people with a history of bipolar disorder. Symptoms may include: greatly increased energy, severe problems sleeping, racing thoughts, reckless behavior, unusually grand ideas, excessive happiness or irritability, or taking more or faster than usual.

Difficulty swallowing

Do not drive, operate heavy machinery, or do other dangerous activities until you know how LATUDA affects you. LATUDA may make you drowsy.

Avoid eating grapefruit or drinking grapefruit juice while you take LATUDA since these can affect the amount of LATUDA in the blood.

Do not take LATUDA if you are allergic to any of the ingredients in LATUDA or take certain medications called CYP3A4 inhibitors or inducers. Ask your health care provider if you are not sure if you are taking any of these medications.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LATUDA and other medicines may affect each other, causing possible serious side effects. LATUDA may affect the way other medicines work, and other medicines may affect how LATUDA works. Your health care provider can tell you if it is safe to take LATUDA with any other medicines. Do not start or stop any other drugs during treatment with LATUDA without talking to your health care provider first.

Before taking LATUDA, tell your health care provider about all of your medical conditions, including if you:

- have or have had heart problems or stroke
- have or have had low or high blood pressure
- have or have had diabetes or high blood sugar, or have a family history of diabetes or high blood sugar
- have or have had high levels of total cholesterol or triglycerides
- have or have had high prolactin levels
- have or have had low white blood cell count
- have or have had kidney or liver problems
- are pregnant or plan to become pregnant. It is not known if LATUDA will harm your unborn baby. Talk to your health care provider about the risk to your unborn baby if you take LATUDA during pregnancy.
- Tell your health care provider if you become pregnant or think you are pregnant during treatment with LATUDA.
- If you become pregnant during treatment with LATUDA, tell your health care provider about registering with the National Pregnancy Registry for Atypical Antipsychotics.
- are breastfeeding or plan to breastfeed. It is not known if LATUDA passes into your breast milk. Talk to your health care provider about the best way to feed your baby during treatment with LATUDA.

The most common side effects of LATUDA include:

- Adults with schizophrenia: sleepiness or drowsiness; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, or muscle stiffness; and nausea
- Adolescents (13 to 17 years) with schizophrenia: sleepiness or drowsiness; nausea; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, muscle stiffness, or tremor, runny nose/nasal inflammation; and vomiting
- Adults with bipolar depression: restlessness or feeling like you need to move around (akathisia); difficulty moving or slow movements; and sleepiness or drowsiness
- Children (10 to 17 years) with bipolar depression: nausea; weight gain; and problems sleeping (insomnia)

These are not all the possible side effects of LATUDA. For more information, ask your health care provider or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion Pharmaceuticals Inc. (Sunovion) is a wholly-owned indirect, wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. and of Sunovion Pharmaceuticals Europe Ltd., based in London, England, and Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company’s websites: www.sunovion.com; www.sunovion.eu; and www.sunovion.ca. Connect with Sunovion on Twitter @Sunovion, LinkedIn, Facebook, and YouTube.

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan operating globally in major pharmaceutical markets, including Japan, the United States, China and the European Union. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as attractive areas, focusing globally in major pharmaceutical markets, including Japan, the United States, and the European Union. Sumitomo Dainippon Pharma Co., Ltd. was established on April 1, 2005, through merger between Sumitomo Pharmaceutical Co., Ltd. and Dainippon Pharmaceutical Co., Ltd. Today, Sumitomo Dainippon Pharma has about 6,500 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.s-d-pharma.com.

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References


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