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News Release

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Sunovion's Latuda[®] (lurasidone HCl) Receives FDA Approval to Treat Adolescents with Schizophrenia

– First treatment approved in five years for adolescents aged 13-17 years with schizophrenia –

Marlborough, Mass., January 28, 2017 – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) today announced that the U.S. Food and Drug Administration (FDA) approved the supplemental New Drug Application (sNDA) for Latuda[®] (lurasidone HCl) for the treatment of schizophrenia in adolescents aged 13 to 17 years. LATUDA is also approved in the U.S. for the treatment of adults with schizophrenia and for the treatment of adults with major depressive episodes associated with bipolar I disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate.

“The impact on development and poor prognosis frequently associated with schizophrenia that begins in adolescence underscores the need for treatment that is both well-tolerated and effective,” said Robert Findling, M.D., M.B.A., Vice President of Psychiatric Services and Research at the Kennedy Krieger Institute, Director of Child and Adolescent Psychiatry at the Johns Hopkins University School of Medicine and a study investigator. “The availability of LATUDA provides healthcare providers with an important new option for helping adolescents with this illness that is chronic and severely disabling.”

The approval is based on results from a randomized, double-blind, placebo-controlled, six-week study in which adolescent patients with schizophrenia received fixed doses of LATUDA 40 mg/day, LATUDA 80 mg/day or placebo. At study endpoint, LATUDA 40 mg/day and 80 mg/day were associated with statistical and clinical improvement in symptoms of schizophrenia compared to placebo. LATUDA was also generally well tolerated with limited effects on weight and metabolic parameters.

“We are pleased that LATUDA’s range of indications has now expanded beyond the adult population to include the treatment of schizophrenia in adolescents aged 13 to 17 years. We believe that LATUDA, as the first such medication in five years approved for adolescent patients with schizophrenia, is an important new treatment option for this difficult to treat illness,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “This approval builds on and reflects our commitment to advancing the treatment of serious psychiatric illness.”

The overall severity, impact on development and poor prognosis of adolescent schizophrenia highlight the need for early detection, prompt diagnosis and effective treatment.² Adolescent schizophrenia has been characterized by a more severe onset of psychotic symptoms than adult-onset schizophrenia and is more likely to be preceded by social and developmental impairments.^{1,2} Additionally, delays to treatment from onset of psychotic symptoms may be two to three times longer for adolescents than adults and are associated with poorer treatment outcomes and response to treatment.^{3,4}

Anyone seeking medical information, patient assistance and 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.

About Schizophrenia

Schizophrenia is a chronic, serious and often severely disabling brain disorder. Symptoms such as hallucinations and delusions usually start between ages 16 and 30.⁷ Other symptoms may include unusual or dysfunctional ways of thinking, agitated body movements, reduced expression of emotions and cognitive symptoms such as poor focus, memory or executive functioning.⁷

Although rare in young children, incidence of schizophrenia rises during adolescence and peaks in early adulthood.² Adolescent schizophrenia is associated with poor functioning prior to the onset of illness and early developmental delays.² Similar types of early developmental and social impairments have been reported in adult-onset schizophrenia, but appear to be more common and severe in adolescents.² A diagnosis of schizophrenia in adolescence may be a predictor of less independence, poorer educational achievement, lower likelihood of employment or access to further education, higher global disability scores and poor social relationships in adulthood.⁸

About LATUDA

LATUDA is used to treat patients with:

- Depressive episodes in bipolar I disorder (bipolar depression) when used alone or with lithium or valproate in adults
- Schizophrenia in adults and adolescents 13 to 17 years of age

The efficacy of LATUDA was established in a 6-week monotherapy study and a 6-week adjunctive therapy study with lithium or valproate in adult patients with bipolar depression. The efficacy of LATUDA in schizophrenia was established in five 6-week controlled studies in adult patients and one 6-week placebo-controlled study in adolescents (13 to 17 years).

The most common side effects of LATUDA include sleepiness or drowsiness; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, muscle stiffness, or tremor; runny nose/nasal inflammation, and nausea.

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 6 weeks, has not been established in controlled studies. Therefore, the physician who elects to use LATUDA for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. The efficacy of LATUDA in the treatment of mania associated with bipolar disorder has not been established.

Please see Important Safety Information, including **Boxed Warnings**, below and full Prescribing Information at www.LATUDA.com.

Important Safety Information and Indications for LATUDA

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

Elderly people with dementia-related psychosis (having lost touch with reality due to confusion and memory loss) treated with this type of medicine are at an increased risk of death compared to patients receiving placebo (sugar pill). LATUDA is not approved for the treatment of patients 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. Depression and other serious mental illnesses are themselves associated with an increase in the risk of suicide. Patients on antidepressants and their families or caregivers should watch for new or worsening depression symptoms, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed. Report any change in these symptoms immediately to the doctor. LATUDA is not approved for use in pediatric patients with depression.

LATUDA can cause serious side effects, including stroke that can lead to death, which can happen in elderly people with dementia who take medicines like LATUDA.

Neuroleptic malignant syndrome (NMS) is a rare but very serious condition that can happen in people who take antipsychotic medicines, including LATUDA. NMS can cause death and must be treated in a hospital. Call your health care provider right away if you become severely ill and have some or all of these symptoms: high fever, excessive sweating, rigid muscles, confusion, or changes in your breathing, heartbeat or blood pressure.

Tardive dyskinesia (TD) is a serious and sometimes permanent side effect reported with LATUDA and similar medicines. Tell your doctor about any movements you cannot control in your face, tongue, or other body parts, as they may be signs of TD. TD may not go away, even if you stop taking LATUDA. TD may also start after you stop taking LATUDA.

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 LATUDA and during therapy. 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.

Increases in triglycerides and LDL (bad) cholesterol and decreases in HDL (good) cholesterol have been reported with LATUDA. You may not have any symptoms, so your health care provider may decide to check your cholesterol and triglycerides during your treatment with LATUDA.

Some patients may gain weight while taking LATUDA. Your doctor should check your weight regularly.

Tell your doctor if you experience any of these:

- feeling dizzy or light-headed upon standing
- decreases in white blood cells (which can be fatal)
- trouble swallowing

LATUDA and medicines like it may raise the level of prolactin. Tell your health care provider if you experience a lack of menstrual periods, leaking or enlarged breasts, or impotence.

Tell your health care provider if you have a seizure disorder, have had seizures in the past, or have conditions that increase your risk for seizures.

Tell your health care provider if you experience prolonged, abnormal muscle spasms or contractions, which may be a sign of a condition called dystonia.

LATUDA can affect your judgment, thinking, and motor skills. You should not drive or operate hazardous machinery until you know how LATUDA affects you.

LATUDA may make you more sensitive to heat. You may have trouble cooling off. Be careful when exercising or when doing things likely to cause dehydration or make you warm.

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

Tell your health care provider about all prescription and over-the-counter medicines you are taking or plan to take, since there are some risks for drug interactions with LATUDA. Tell your health care provider if you are allergic to any of the ingredients of 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.

Avoid drinking alcohol while taking LATUDA.

Tell your health care provider if you are pregnant or if you are planning to get pregnant. Avoid breastfeeding while taking LATUDA.

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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 is a global biopharmaceutical company focused on the innovative application of science and medicine to help people with serious medical conditions. Sunovion's vision is to lead the way to a healthier world. The company's spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. With patients at the center of everything it does, Sunovion has charted new paths to life-transforming treatments that reflect ongoing investments in research and development and an unwavering commitment to support people with

psychiatric, neurological and respiratory conditions. Sunovion's track record of discovery, development and commercialization of important therapies has included Brovana[®] (arformoterol tartrate), Latuda[®] (lurasidone HCl), and most recently Aptiom[®] (eslicarbazepine acetate).

Headquartered in Marlborough, Mass., Sunovion is an indirect, wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. Sunovion Pharmaceuticals Europe Ltd., based in London, England, Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, and Sunovion CNS Development Canada ULC, based in Toronto, Ontario, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's web sites: www.sunovion.com, www.sunovion.eu and www.sunovion.ca. Connect with Sunovion on [Twitter](#), [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 the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

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For a copy of this release, visit Sunovion's web site at www.sunovion.com

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⁸ Hollis, C. *Am J Psychiatry*. 2000; 157:1652-1659.