Sunovion to Present Data on LATUDA® (lurasidone HCI) at the 25th European Congress of Psychiatry

Release Date:
Friday, March 31, 2017 8:00 am EDT

Terms:

- Date line: MARLBOROUGH, Mass. – Sunovion will present two research posters and deliver two oral research presentations on LATUDA® (lurasidone HCI) at the 25th European Congress of Psychiatry (EPA 2017) to be held April 1-4, 2017, in Florence, Italy.

LATUDA was recently approved by the U.S. Food and Drug Administration (FDA) 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 disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate. LATUDA is approved in the EU for the treatment of adult patients with schizophrenia.

“We are pleased to present data from several studies including a Phase 3 clinical trial of LATUDA in adolescents with schizophrenia that supported the First U.S. approval for this indication in five years,” said Anthony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion. Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “We remain committed to addressing unmet medical needs for people living with mental illness, and these presentations reflect our ongoing efforts to facilitate informed discussion of LATUDA across the global medical community.”

Other key presentations will include data on the effects of continued treatment with LATUDA in adults with bipolar depression and a post-hoc analysis examining the efficacy of LATUDA in major depressive disorder with mixed features (MDD-MF).

Sunovion data presentations include:

- Poster EW0404: Lurasidone for the Treatment of Major Depressive Disorder with Mixed Features: Do Manic Symptoms Moderate Treatment Response? (Monday, April 3, 12:30-13:15 CET, 6:30-7:15 a.m. ET)
- Poster EW0304: Lurasidone Adjunctive to Lithium or Valproate for Prevention of Recurrence in Bipolar I Disorder (Monday, April 3, 12:30-13:15 CET, 6:30-7:15 a.m. ET)

About LATUDA

LATUDA is approved in the U.S. and Canada for the treatment of adult patients with schizophrenia and for the treatment of depressive episodes associated with bipolar disorder (bipolar depression) as monotherapy or as adjunctive therapy with lithium or valproate. LATUDA is also approved in the U.S. for the treatment of adolescent patients’ ages 13 to 17 years with schizophrenia.

LATUDA is approved for the treatment of adult patients with schizophrenia in the EU, Switzerland, Austria, Taiwan, Russia, Singapore, Thailand and Hong Kong.

(U.S.) 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.

Antidepressants 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, feelings, behaviors, thoughts, or actions. 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.

Neuropsychiatric symptoms (NPS) are a rare but very serious condition that can happen in people who take antipsychotic medicines, including LATUDA. NPS 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, rapid heart rate, confusion, or changes in your breathing, heart rate, 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.

In rare cases, LATUDA may cause an increase in blood sugar 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: 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.

Intravenous or I.V. (intravenous) injection of a medicine is 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.

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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 OTC 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.

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; nervous nose/nasal inflammation, and nausea.

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.

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