Sunovion to Present Data on Latuda® (Lurasidone HCl) and Novel Investigational Psychotropic SEP-363856 at the 55th Annual Meeting of the American College of Neuropsychopharmacology

Release Date: Friday, December 2, 2016 8:00 am EST

Terms:

- Presentations include data from studies in bipolar I disorder, schizophrenia and major depressive disorder with mixed features -

MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc. (Sunovion) will present four research posters on Latuda® (lurasidone HCl) and two research posters on novel investigational psychotropic SEP-363856 at the 55th Annual Meeting of the American College of Neuropsychopharmacology (ACNP), being held December 4-8 in Hollywood, Florida.

LATUDA is an atypical antipsychotic agent indicated for the treatment of adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression) both as monotherapy and as adjunctive therapy with lithium or valproate, and for the treatment of adult patients with schizophrenia. SEP-363856 is an investigational psychotropic agent being studied as a treatment for patients with schizophrenia or Parkinson’s disease psychosis.

“We’re pleased to present a broad spectrum of data, including Phase 1 studies of SEP-363856, which we believe has the potential to treat both the positive and negative symptoms of schizophrenia, as well as the hallucinations and delusions commonly experienced by patients with Parkinson’s disease,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer, Sunovion. “We remain committed to advancing the next generation of therapies that will address the significant needs that remain for people living with mental illness.”

Key data presented for LATUDA will include results from a study evaluating LATUDA for the treatment of schizophrenia in adolescents’ ages 13 to 17 years old and new post-hoc analyses examining the effect of LATUDA on recurrence prevention in patients with bipolar depression. Data presentations include:

- Poster M269: Effect of Lurasidone Dose on Recurrence Prevention in Patients With Bipolar I Disorder: Post Hoc Analysis of a Placebo-Controlled Randomized Withdrawal Study (Monday, December 5, 5:30 p.m. - 7:30 p.m. ET)
- Poster M81: Lurasidone for Prevention of Recurrence in Patients With Bipolar I Disorder: Comparison Of Adjunctive Therapy With Lithium vs. Valproate (Monday, December 5, 5:30 p.m. - 7:30 p.m. ET)
- Poster W215: The Efficacy and Safety of Lurasidone in Adolescent Patients With Schizophrenia: A 6-Week, Double-Blind, Placebo-Controlled, Multicenter Study (Wednesday, December 7, 5:30 p.m. - 7:30 p.m. ET)
- Poster W91: Lurasidone for the Treatment of Major Depressive Disorder With Mixed Features: Does Number of Manic Symptoms Moderate Treatment Response? (Wednesday, December 7, 5:30 p.m. - 7:30 p.m. ET)

Key data presented for SEP-363856 will include results from two Phase 1 studies that assessed the tolerability and effect on brain neurocircuitry of this novel non-D2 mechanism of action agent. Data presentations include:

- Poster M166: A Phase 1 Open Label Safety and Tolerability Study of SEP-363856, a Novel Non-D2 Mechanism of Action Molecule, in Patients With Schizophrenia (Monday, December 5, 5:30 p.m. - 7:30 p.m. ET)
- Poster T173: A Phase 1 Neuroimaging Study of SEP-363856 in Healthy Volunteers with High or Low Schizotypy (Tuesday, December 6, 5:30 p.m. - 7:30 p.m. ET)

About LATUDA

LATUDA is FDA-approved to treat adult patients with:

- Major depressive episodes associated with bipolar I disorder (bipolar depression) when used alone or with lithium or valproate
- Schizophrenia

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 the treatment of adult patients with schizophrenia was established in five 6-week controlled studies. 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.

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; and nausea.

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

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 patients 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 treating elderly patients with dementia-related psychosis.
- Antidepressants have increased the risk of suicidal thoughts and actions in some children, teenagers, and young adults. Patients of all ages starting treatment should be watched closely for worsening of depression, suicidal thoughts or actions, unusual changes in behavior, agitation, and irritability. Patients, families, and caregivers should pay close attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is increased. Report any change in these symptoms immediately to the doctor. LATUDA is not approved for patients under the age of 18 years.

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 healthcare 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 healthcare provider should check your blood sugar before you start LATUDA and during therapy.

Call your healthcare 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 healthcare 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 healthcare provider if you experience a lack of menstrual periods, leaking or enlarged breasts, or impotence.

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

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

Avoid drinking alcohol while taking LATUDA.

Tell your healthcare provider if you are pregnant or if you are planning to become 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; and nausea.

These are not all the possible side effects of LATUDA. For more information, ask your healthcare 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 SEP-363856

SEP-363856 is a potential psychotropic agent with a novel non-D2 mechanism of action. The molecular target(s) responsible for the profile of effects is unknown, but may include agonism at 5-HT1A and TAAR1 (trace amine-associated receptor 1) receptors. SEP-363856 is being studied in a global Phase 2 program, and preclinical models suggest that SEP-363856 may be able to treat the positive and negative symptoms of schizophrenia as well as Parkinson’s disease psychosis. Clinical experience to date demonstrates an excellent pharmacokinetic (PK) profile, central effects in schizophrenic patients and a safety profile supporting further clinical development.

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, the Company 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 Brevoxol® (aripiprazole tartrate), Latuda® (laruxifene HCl), and most recently Aptiom® (eslicarbazepine acetate).


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 [12].

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