Sunovion Pharmaceuticals Inc. to Present New Data on Latuda® (lurasidone HCl) at the 167th Annual Meeting of the American Psychiatric Association

Marlborough, Mass., May 1, 2014 – Sunovion Pharmaceuticals Inc. will present 20 research posters on Latuda® (lurasidone HCl), 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, at the 167th Annual Meeting of the American Psychiatric Association (APA). The meeting will be held May 3-7 in New York, New York.

“We are pleased to present a broad spectrum of research including new data and analyses from bipolar depression and schizophrenia studies aimed at better understanding the short- and long-term efficacy and metabolic safety profile of LATUDA,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer, Sunovion Pharmaceuticals Inc. “Providing healthcare practitioners with information that is relevant to the real world treatment of people living with mental illness is critically important and is at the cornerstone of our commitment to the psychiatric community.”

Bipolar Depression Research Highlights

Key data presented will include results from new post-hoc analyses of the pivotal studies that supported the U.S. Food and Drug Administration (FDA) approval of LATUDA in bipolar depression in June 2013 and the recent approval by Health Canada (March 2014). These data examine the effect of LATUDA on core symptoms of bipolar depression, onset and duration of response, as well as measures of short- and long-term metabolic safety. New long-term data from an open label extension study will also be presented. Following are highlights from these presentations:

- Poster NR8-172: Lurasidone for the Treatment of Bipolar Depression: Current State of the Evidence (Tuesday, May 6, 2:30 – 4:00 p.m. ET)

- Poster NR8-58: Lurasidone Treatment for Bipolar I Depression: Effect on Core Depressive Symptoms (Tuesday, May 6, 2:30 – 4:00 p.m. ET)
• Poster NR6-53: Early Sustained Response with Lurasidone in the Treatment of Bipolar I Depression (Monday, May 5, 2:30 – 4:00 p.m. ET)

• Poster NR6-62: Short- and Longer-Term Treatment with Lurasidone in Patients with Bipolar I Depression: Effect on Metabolic Syndrome (Monday, May 5, 2:30 – 4:00 p.m. ET)

• Poster NR6-55: Lurasidone in Bipolar I Depression: A 24 Week, Open-Label Extension Study (Monday, May 5, 2:30 – 4:00 p.m. ET)

• Poster NR6-56: Lurasidone Treatment For Bipolar I Depression: Effects On Quality Of Life And Patient Functioning (Monday, May 5, 2:30 – 4:00 p.m. ET)

**Schizophrenia Research Highlights**
Data examining the efficacy and safety of long-term use of LATUDA in adult patients with schizophrenia will be presented for the first time in the U.S. Results from this maintenance study will be submitted as a supplemental New Drug Application (sNDA) to the FDA. Use of LATUDA as a maintenance treatment has not been approved by the FDA. Highlights from presentations on this study and other post-hoc analyses are as follows:

• Poster NR8-151: A Double-Blind, Placebo-Controlled, Randomized Withdrawal Study of Lurasidone for the Maintenance of Efficacy in Patients with Schizophrenia (Tuesday, May 6, 2:30 – 4:00 p.m. ET)

• Poster NR8-140: An Open-Label Extension Study of Lurasidone Safety and Efficacy in Patients with Schizophrenia Previously Randomized to Lurasidone or Risperidone (Tuesday, May 6, 2:30 – 4:00 p.m. ET)

**Health Economics and Outcomes Research (HEOR) Highlights**
These posters will assess the impact of LATUDA on adherence rates and calculated quality of life outcomes, as well as other HEOR parameters. Highlights include:

• Poster NR6-69: Comparison of Treatment Adherence to Atypical Antipsychotics Among Adults with Bipolar Disorder in a Medicaid Population (Monday, May 5, 2:30 – 4:00 p.m. ET)

• Poster NR8-135: Health-Related Quality of Life Outcomes Among Patients Switched to Lurasidone from Other Antipsychotics: Results of a 6 Month Extension Study Among Patients with Schizophrenia (Tuesday, May 6, 2:30 – 4:00 p.m. ET)

• Poster NR8-147: Risk Reduction and Numbers Needed to Treat to Avoid Metabolic Syndrome: 12-Month Cardiometabolic Parameters Changes Among Schizophrenia Subjects Treated With Lurasidone or Quetiapine XR (Tuesday, May 6, 2:30 – 4:00 p.m. ET)

These represent highlights from the 20 poster presentations; however, all posters are available for viewing on Monday, May 5 and Tuesday, May 6 from 2:30 – 4:00 p.m. ET at the Jacob K. Javits Convention Center, Level 3, Halls 3A/3B.
About LATUDA
LATUDA is used to treat adult patients with:

- Depressive episodes in 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.

INDICATIONS AND USAGE
LATUDA is indicated for treatment of major depressive episodes associated with bipolar I disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate, and for the treatment of 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, and in five 6-week controlled studies of adult patients with schizophrenia. 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.

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 changed. 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 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; 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.

**INDICATIONS**

LATUDA is used to treat adult patients with:

- Depressive episodes in bipolar I disorder (bipolar depression) when used alone or with lithium or valproate
- Schizophrenia

**About Sunovion Pharmaceuticals Inc. (Sunovion)**

Sunovion is a leading pharmaceutical company dedicated to discovering, developing and commercializing therapeutic products that advance the science of medicine in the Psychiatry & Neurology and Respiratory disease areas. Sunovion’s drug development program, together with its corporate development and licensing efforts, has yielded a portfolio of pharmaceutical products including Aptiom® (eslicarbazepine acetate), Latuda® (lurasidone HCl) tablets, Lunesta® (eszopiclone) tablets, Xopenex® (levalbuterol HCl) inhalation solution, Xopenex HFA® (levalbuterol tartrate) inhalation aerosol, Brovana® (arformoterol.
tartrate) inhalation solution, Omnaris® (ciclesonide) nasal spray, Zetonna® (ciclesonide) nasal aerosol and Alvesco® (ciclesonide) inhalation aerosol.


**About Dainippon Sumitomo Pharma Co., Ltd. (DSP)**
DSP is a top-ten listed pharmaceutical company in Japan with a diverse portfolio of pharmaceutical, animal health and food and specialty products. DSP aims to produce innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. DSP is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, DSP has about 7,000 employees worldwide. Additional information about DSP is available through its corporate website at www.ds-pharma.com

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