Sunovion Pharmaceuticals Inc.
84 Waterford Drive, Marlborough, MA 01752-7010
Tel 508-481-6700

News Release

Contact: Susan Adler Alesina
Vice President, Corporate Communications
Sunovion Pharmaceuticals Inc.
508-481-6700
susan.alesina@sunovion.com

LATUDA® (lurasidone HCl) Shown to be Non-Inferior to SEROQUEL XR® (quetiapine fumarate XR) in Risk for Relapse in a 12-Month, Double-Blind Extension Study of Adult Patients with Schizophrenia

Marlborough, Mass., October 27, 2011 – Sunovion Pharmaceuticals Inc. today announced results from a 12-month, double-blind extension study comparing LATUDA to SEROQUEL XR in adult patients with schizophrenia. The results of the extension study demonstrated LATUDA to be non-inferior to SEROQUEL XR in risk for relapse.

The primary efficacy endpoint was time to relapse of psychotic symptoms, applying pre-specified relapse criteria. The primary analysis utilized a Cox proportional hazards model to assess non-inferiority of LATUDA compared to SEROQUEL XR. Results of this analysis showed a hazard ratio of 0.728 (indicating a 27% lower risk of relapse for LATUDA), with an upper limit of the 95% CI of 1.295. Since the protocol pre-specified margin for non-inferiority was 1.93, this study successfully demonstrated non-inferiority of LATUDA compared to SEROQUEL XR.

Adverse events (greater than or equal to 5%) associated with LATUDA included akathisia, headache, insomnia, anxiety, increased weight and parkinsonism. Adverse events associated with SEROQUEL XR (greater than or equal to 5%) included schizophrenia, headache, insomnia, psychotic disorder, increased weight and agitation. LATUDA was also associated with low rates of weight gain and metabolic changes.

About the "PEARL 3*" Extension Study

The double-blind extension study followed a core six-week, double-blind, placebo-controlled study (PEARL 3) where patients were randomized to treatment with one of the following: LATUDA 80 mg/day, LATUDA 160 mg/day, SEROQUEL XR 600 mg/day or placebo. A total of 292 patients entered the extension study.

Patients treated with LATUDA 80 mg/day or 160 mg/day in the preceding PEARL 3 study were treated with a fixed dose of LATUDA 120 mg/day for the first week of the extension study, and were then flexibly dosed (LATUDA 40 mg/day – 160 mg/day), at the investigator's discretion, for up to 52 weeks (N=151).

Patients treated with SEROQUEL XR 600 mg/day in the preceding PEARL 3 study were treated with SEROQUEL XR 600 mg/day for the first week of the extension study, and were then flexibly dosed (SEROQUEL XR 200 mg/day – 800 mg/day) for up to 52 weeks (N=85).

*PEARL 3 (**P**rogram to **E**valuate the **A**ntipsychotic **R**esponse to **L**urasidone) was a six-week, double-blind, placebo-controlled study to evaluate the efficacy of LATUDA in adult patients with schizophrenia.

Patients on placebo in the PEARL 3 study (N=56) were transitioned to LATUDA in the extension study in a manner similar to those patients who had been taking LATUDA (results of the primary and secondary analyses discussed below do not include PEARL 3 study placebo patients who entered the extension study).

The mean age was 37.1 years for the LATUDA treatment group and 38.5 years for the SEROQUEL XR group. The gender distribution was 72% male for the LATUDA group and 61% male for the SEROQUEL XR group.

Other key findings for this 12-month, double-blind extension study are as follows:

- **Probability of Relapse**:[1] The probability of relapse at month 12 (based on Kaplan-Meier survival analysis) was 23.7% for LATUDA and 33.6% for SEROQUEL XR.
- **Discontinuation due to treatment failure** (insufficient clinical response or adverse events): Rates were 16% for LATUDA and 26% for SEROQUEL XR.

Additional findings from the acute baseline (start of the PEARL 3 study) to the 12-month extension study endpoint are outlined below.[2]

- **PANSS Total Scores:** LS mean changes were: -34.6 for LATUDA and -25.7 for SEROQUEL XR (p=0.006).
- **Weight**: Mean changes were +0.7 kg (1.5 lbs) for LATUDA and +1.2 kg (2.6 lbs) for SEROQUEL XR.
- **Cholesterol**: Median changes were 0.0 mg/dL increase for LATUDA and +4.0 mg/dL increase for SEROQUEL XR.
- **Triglycerides**: Median changes were -18.0 mg/dL for LATUDA and -7.0 mg/dL for SEROQUEL XR.
- **Glucose**: Median changes were +1.0 mg/dL for both LATUDA and SEROQUEL XR.

[1]*The pre-specified relapse population definition included all patients who demonstrated clinical response to six weeks of treatment with either LATUDA or SEROQUEL XR and received at least one dose of study medication in the extension study.*
[2] *Weight and laboratory measure data were obtained from 12-month observed case analysis.*

"This study presents an important opportunity to understand how LATUDA compares to another widely used atypical agent, SEROQUEL XR. Long-term, double-blind data such as those provided in this year-long study are essential to aid physicians in choosing the best medication for their patients, balancing efficacy and side effects. More of such studies are needed and would improve patient care," said Steven G. Potkin, M.D., professor, Department of Psychiatry and Human Behavior, University of California, Irvine. "In this study, the group of patients who took LATUDA experienced fewer relapses and lower rates of weight gain and other metabolic concerns than those taking SEROQUEL XR."

"Physicians and payers are increasingly interested in results from comparative assessments of active agents, so that use of scarce resources can be optimized. We conducted this double-blind study to evaluate relapse risk over a 12-month period for LATUDA and SEROQUEL XR in patients with schizophrenia, as relapse is a key driver of both costs and clinical outcome. We are pleased to see that the study successfully showed LATUDA to be non-inferior to SEROQUEL XR in terms of risk of relapse and to have a lower discontinuation rate due to treatment failure," said Antony Loebel, M.D., executive vice president, Clinical Development and Medical Affairs at Sunovion Pharmaceuticals Inc.

LATUDA received U.S. Food and Drug Administration (FDA) approval for the treatment of schizophrenia on October 28, 2010 and is available in pharmacies across the U.S. and Puerto Rico. A supplemental New Drug Application for a 160 mg/day dose of LATUDA is under review at the FDA but has not been approved for use.

The full study findings will be presented at a future psychiatric medical congress. The press release announcing results from the core study (PEARL 3) can be viewed at: http://www.sunovion.com/news/pressReleases/20101208.pdf.

About LATUDA

LATUDA is an atypical antipsychotic indicated for the treatment of patients with schizophrenia. Efficacy was established in four 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 recommended starting dose for LATUDA is 40mg/day taken with food (at least 350 calories) with no initial dose titration required. LATUDA has been shown to be effective in dose ranges of 40 mg/day to 120 mg/day. In the 6-week controlled trials, there was no suggestion of added benefit with the 120 mg/day dose, but there was a dose-related increase in certain adverse reactions. Therefore, the maximum recommended dose is 80 mg/day. For patients with moderate to severe renal or hepatic impairment, the dose of LATUDA should not exceed 40 mg/day. LATUDA should not be administered with strong CYP3A4 inhibitors such as ketoconazole or strong CYP3A4 inducers such as rifampin.

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

IMPORTANT SAFETY INFORMATION FOR LATUDA

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5% compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. LATUDA is not approved for the treatment of patients with dementia-related psychosis.

CONTRAINDICATIONS

LATUDA is contraindicated in any patient with a known hypersensitivity to lurasidone HCl or any components in the formulation. Angioedema has been observed with lurasidone. LATUDA is contraindicated with strong CYP3A4 inhibitors (e.g., ketoconazole) and strong CYP3A4 inducers (e.g., rifampin).

WARNINGS AND PRECAUTIONS

Cerebrovascular Adverse Reactions, Including Stroke: In placebo-controlled trials with risperidone, aripiprazole, and olanzapine in elderly subjects with dementia, there was a higher incidence of cerebrovascular adverse reactions (cerebrovascular accidents and transient ischemic attacks) including fatalities compared to placebo-treated subjects. LATUDA is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported with administration of antipsychotic drugs, including LATUDA. NMS can cause hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Tardive Dyskinesia (TD): TD is a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements that can develop in patients with antipsychotic drugs. There is no known treatment for established cases of TD, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. The risk of developing TD and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Given these considerations, LATUDA should be prescribed in a manner that is most likely to minimize the occurrence of TD. If signs and symptoms appear in a patient on LATUDA, drug discontinuation should be considered.

Metabolic Changes

Hyperglycemia and Diabetes Mellitus: Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Dyslipidemia: Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.

Weight Gain: Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Hyperprolactinemia: As with other drugs that antagonize dopamine D2 receptors, LATUDA elevates prolactin levels. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds. In short-term, placebo-controlled studies, the increase in prolactin was greater in LATUDA-treated female patients; the median change from baseline to endpoint for females was 1.5 ng/mL and was 1.1 ng/mL in males. The increase in prolactin concentrations was dose-dependent. The proportion of female patients with prolactin elevations ≥5x ULN was 8.3% for LATUDA-treated patients versus 1% for placebo-treated female patients. The proportion of male patients with prolactin elevations > 5x ULN was 1.9% versus 0.6% for placebo-treated male patients.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia/neutropenia has been reported during treatment with antipsychotic agents. Agranulocytosis (including fatal cases) has been reported with other agents in the class. Patients with a preexisting low white blood cell count (WBC) or a history of drug induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy, and LATUDA should be discontinued at the first sign of a decline in WBC in the absence of other causative factors.

Orthostatic Hypotension and Syncope: LATUDA may cause orthostatic hypotension. LATUDA should be used with caution in patients with known cardiovascular disease (e.g., heart failure, history of myocardial infarction, ischemia, or conduction abnormalities), cerebrovascular disease, or conditions that predispose the patient to hypotension (e.g., dehydration, hypovolemia, and treatment with antihypertensive medications). Monitoring of orthostatic vital signs should be considered in all patients who are vulnerable to hypotension.

Seizures: LATUDA should be used cautiously in patients with a history of seizures or with conditions that lower seizure threshold (e.g., Alzheimer's dementia).

Potential for Cognitive and Motor Impairment: In short-term, placebo-controlled trials, somnolence was reported in 22.3% (224/1004) of patients treated with LATUDA compared to 9.9% (45/455) of placebo patients, respectively. The frequency of somnolence increases with dose. Patients should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that therapy with LATUDA does not affect them adversely.

Body Temperature Regulation: Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing LATUDA for patients who will be experiencing conditions that may contribute to an elevation in core body temperature, e.g., exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration.

Suicide: The possibility of suicide attempt is inherent in psychotic illness and close supervision of high-risk patients should accompany drug therapy. Prescriptions for LATUDA should be written for the smallest quantity of tablets consistent with good patient management in order to reduce the risk of overdose.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia. LATUDA is not indicated for the treatment of dementia-related psychosis, and should not be used in patients at risk for aspiration pneumonia.

DRUG INTERACTIONS
Drug Interactions: Given the primary CNS effects of LATUDA, caution should be used when it is taken in combination with other centrally acting drugs and alcohol.

ADVERSE REACTIONS
Commonly Observed Adverse Reactions (≥5% and at least twice that for placebo): The most commonly observed adverse reactions in patients treated with LATUDA in short-term clinical studies were somnolence, akathisia, nausea, parkinsonism, and agitation.

Before prescribing LATUDA, please read the full Prescribing Information, including **Boxed Warning** at www.LATUDA.com.

About Schizophrenia
Schizophrenia is a chronic, disabling and serious brain disorder that affects approximately 2.4 million American adults or 1 in 100 people. Schizophrenia is characterized by symptoms such as hallucinations, delusions, disorganized thinking, lack of emotion, lack of energy, as well as problems with memory, attention and the ability to plan, organize and make decisions.

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 central nervous system (CNS) and respiratory disease areas and improve the lives of patients and their families. Sunovion's drug development program, together with its corporate development and licensing efforts, has yielded a portfolio of pharmaceutical products including LATUDA® brand lurasidone HCl, LUNESTA® brand eszopiclone, XOPENEX® brand levalbuterol HCl Inhalation Solution, XOPENEX HFA® brand levalbuterol tartrate inhalation aerosol, BROVANA® brand aformoterol tartrate inhalation solution, OMNARIS® brand ciclesonide nasal spray and ALVESCO® brand ciclesonide HFA inhalation aerosol.

Sunovion, an indirect, wholly-owned subsidiary of Dainippon Sumitomo Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at www.sunovion.com.

About Dainippon Sumitomo Pharma Co., Ltd. (DSP)
DSP is a multi-billion dollar, 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 CNS field, which has been designated as the key therapeutic area and will also focus in on other specialty disease categories with significant unmet medical needs, which are designated as frontier therapeutic areas. DSP is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, DSP has more than 7,000 employees worldwide. Additional information about DSP is available through its corporate website at www.ds-pharma.com.

LATUDA is a registered trademark of Dainippon Sumitomo Pharma Co., Ltd. LUNESTA, XOPENEX, XOPENEX HFA and BROVANA are registered trademarks of Sunovion Pharmaceuticals Inc. OMNARIS and ALVESCO are registered trademarks of Nycomed GmbH.

SEROQUEL XR® (quetiapine fumarate XR) is manufactured by AstraZeneca.

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

###