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

News Release

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

Latuda® (lurasidone HCl) Significantly Improves Symptoms of Schizophrenia in Fifth Positive Placebo-Controlled Study

Findings Demonstrate LATUDA 80 and 160 mg/day Significantly More Effective than Placebo

MARLBOROUGH, Mass., December 8, 2010 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced the results of the PEARL 3 study, the third phase 3 worldwide clinical trial of Latuda® (lurasidone HCl) tablets, a once-daily atypical antipsychotic agent recently approved by the U.S. Food and Drug Administration (FDA) for the treatment of patients with schizophrenia. In this six-week, placebo-controlled trial, both fixed doses of LATUDA 80 and 160 mg once-daily, demonstrated statistically significant improvement in symptoms of schizophrenia versus placebo across both primary and secondary efficacy measures. LATUDA was also well tolerated with a relatively low discontinuation rate. The LATUDA 160 mg/day dose has not been reviewed or approved by FDA. The study was presented today at the American College of Neuropsychopharmacology (ACNP) 49th Annual Meeting in Miami, Florida.

"The recent FDA approval of LATUDA provides an additional treatment option for patients with schizophrenia. The PEARL 3 study data demonstrating clear efficacy coupled with weight and metabolic properties similar to placebo add to our understanding of the future role of LATUDA in

Sunovion Pharmaceuticals Inc.
84 Waterford Drive, Marlborough, MA 01752-7010
508-481-6700 Fax 508-357-7490

managing the debilitating symptoms that can be challenging to treat," said Steven G. Potkin, M.D., professor, department of psychiatry and human behavior, University of California, Irvine and presenting author of the study.

The **PEARL 3** study (**P**rogram to **E**valuate the **A**ntipsychotic **R**esponse to **L**urasidone) was part of an extensive worldwide clinical development program involving more than 2,900 subjects, which evaluated the safety and efficacy of LATUDA for the treatment of adult patients with 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.

PEARL 3 Key Study Findings

The PEARL 3 study was a double-blind, fixed-dose, placebo-controlled, six-week clinical trial involving 488 patients with schizophrenia and was conducted at 64 sites worldwide. The study had three active treatment arms: LATUDA 80 mg/day and 160 mg/day, and quetiapine extended-release (XR)* 600 mg/day. The use of quetiapine XR was intended to establish assay sensitivity; the study was not designed to directly compare the efficacy of quetiapine and LATUDA. Patients were diagnosed with schizophrenia (using DSM-IV criteria) and were required to have an acute exacerbation of psychotic symptoms with a PANSS [the Positive and Negative Syndrome Scale] total score of 80 or higher at study baseline.

LATUDA 80 and 160 mg once daily were significantly more effective than placebo (-22.2 and -26.5 vs. -10.3 placebo) at Week 6 in the treatment of patients with schizophrenia, with improvements seen as early as day four on the PANSS, the primary efficacy measure. A total of 65% of patients on LATUDA 80 mg/day and 79% of patients on LATUDA 160 mg/day demonstrated a 20% or more improvement on the PANSS total score from baseline versus 41% on placebo at Week 6/Last Observation Carried Forward (LOCF) endpoint.

In addition, both LATUDA dose groups were significantly more effective than placebo on the Clinical Global Impressions Severity scale (CGI-S), the key secondary efficacy endpoint, as early as week one. CGI-S score changes from baseline for LATUDA 80 and 160 mg/day versus placebo were -1.5 and -1.7 vs. -0.9, respectively, at Week 6.

Sunovion Pharmaceuticals Inc.
84 Waterford Drive, Marlborough, MA 01752-7010
508-481-6700 Fax 508-357-7490

Based on the results of this study, the overall safety profile of the drug is not changed. LATUDA 80 and 160 mg/day treatment was well tolerated with a lower overall discontinuation rate than placebo (29% and 23%, respectively vs. 39% placebo), while adverse event-related discontinuations were comparable to placebo (4% and 3%, respectively vs. 4% placebo). The most commonly reported adverse events for LATUDA 80 and 160 mg/day (greater than 5% and at least twice the rate of placebo) were akathisia (8.0% and 7.4% vs. 0.8% placebo); nausea (8.0% and 6.6% vs. 3.3% placebo); parkinsonism (5.6% and 6.6% vs. 0% placebo); dizziness (4.8% and 5.8% vs. 1.7% placebo); and somnolence (4.0% and 6.6% vs. 0.8% placebo).

The effect of both LATUDA doses (80 and 160 mg/day) on weight was similar to placebo: mean weight change was 0.6 kg (1.3 lbs) for both doses compared to 0.1 kg (0.2 lbs) for placebo, at Week 6/LOCF endpoint. Median changes in total cholesterol and other lipid measurements for both LATUDA doses (80 and 160 mg/day) were also similar to placebo: total cholesterol -4.0 mg/dL and -7.5 mg/dL as compared to -7.0 mg/dL placebo; and triglycerides -2.0 mg/dL and -9.0 mg/dL as compared to -9.0 mg/dL placebo, respectively, at Week 6/LOCF endpoint.

"The PEARL 3 results are an important addition to the LATUDA clinical database, and our fifth placebo-controlled trial demonstrating efficacy in schizophrenia," said Antony Loebel, M.D., executive vice president, Clinical Research and Medical Affairs at Sunovion Pharmaceuticals Inc. "In this study once-daily LATUDA was given in the evening with food. This regimen was well-tolerated at the doses studied."

Quetiapine XR Key Study Findings

Quetiapine XR 600 mg/day produced significantly greater improvements than placebo at Week 6 on both the PANSS total score (-27.8 vs. -10.3 placebo) and CGI-S (-1.7 vs. -0.9 placebo). A total of 79% of patients on quetiapine XR demonstrated a 20% or more improvement on the PANSS total score from baseline versus 41% on placebo at Week 6/LOCF endpoint. Quetiapine XR was associated with an overall discontinuation rate of 19% vs. 39% placebo. The most commonly reported adverse events for quetiapine XR (greater than 5% and at least twice the rate of placebo) were dizziness (13.4% vs. 1.7% placebo), somnolence (13.4% vs. 0.8% placebo), increased weight (6.7% vs. 0.8% placebo), constipation (6.7% vs 2.5% placebo); dry mouth (7.6% vs. 0.8% placebo); arthralgia (5.9% vs. 0.8% placebo) and, upper respiratory tract infection (5.0% vs. 0.8% placebo).

Patients given quetiapine XR reported a 2.1 kg (4.6 lbs) increase in mean weight gain vs. 0.1 kg (0.2 lbs) placebo, at Week 6/LOCF endpoint. Patients treated with quetiapine XR had a greater increase in lipid parameters versus placebo (median change: cholesterol 6.0 mg/dL vs. -7.0 mg/dL placebo; and triglycerides 8.0 mg/dL vs. -9.0 mg/dL placebo at Week 6/LOCF endpoint).

Sunovion Pharmaceuticals Inc.
84 Waterford Drive, Marlborough, MA 01752-7010
508-481-6700 Fax 508-357-7490

About Latuda® (lurasidone HCl) tablets

LATUDA is an atypical antipsychotic indicated for the treatment of patients with schizophrenia. The efficacy of LATUDA in schizophrenia 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.

Dosage and Administration

The recommended starting dose of LATUDA is 40 mg once daily. LATUDA should be taken with food. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range 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.

The LATUDA 160 mg/day dose has not been reviewed or approved by FDA.

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 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. LATUDA should not be used in combination with a strong CYP3A4 inhibitor or inducer.

Cerebrovascular Adverse Events: 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.

Sunovion Pharmaceuticals Inc.
84 Waterford Drive, Marlborough, MA 01752-7010
508-481-6700 Fax 508-357-7490

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, irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia. Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Management should include immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, intensive symptomatic treatment and medical monitoring, and treatment of any concomitant serious medical problems.

Tardive Dyskinesia (TD): The risk of developing TD and the potential for it to become irreversible may increase as the duration of treatment and the total cumulative dose increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing should be consistent with the need to minimize TD. If signs and symptoms appear, discontinuation should be considered.

Hyperglycemia and Diabetes Mellitus: Hyperglycemia, in some cases associated with ketoacidosis, hyperosmolar coma, or death, has been reported in patients treated with atypical antipsychotics. Patients with risk factors for diabetes mellitus who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of and 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 also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of antidiabetic treatment despite discontinuation of the antipsychotic drug.

Weight Gain: In short-term schizophrenia studies, there were differences in mean weight gain between LATUDA-treated and placebo-treated patients. The mean weight gain was 0.75 kg for LATUDA-treated patients compared to 0.26 kg for placebo-treated patients. The proportion of patients with a ≥7% increase in body weight was 5.6% versus 4.0% for placebo-treated patients. In longer-term studies (primarily open-label extension studies), LATUDA was associated with a mean change in weight of -0.38 kg at week 24 (n = 531), -0.47 kg at week 36 (n = 303) and -0.71 kg at week 52 (n = 244).

Orthostatic Hypotension, Syncope, and Other Hemodynamic Effects: LATUDA may induce orthostatic hypotension and syncope. LATUDA should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions that predispose them to hypotension and in the elderly. LATUDA should be used cautiously when treating patients who receive treatment with other drugs that can induce hypotension, bradycardia, respiratory or central nervous system depression. Monitoring of orthostatic vital signs should be considered in all such patients, and a dose reduction should be considered if hypotension occurs.

Leukopenia, Neutropenia, and Agranulocytosis: In clinical trial and postmarketing experience, events of leukopenia/neutropenia have been reported temporally related to antipsychotic agents. Patients with a preexisting low white blood cell count (WBC) or a history of 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.

Sunovion Pharmaceuticals Inc.
84 Waterford Drive, Marlborough, MA 01752-7010
508-481-6700 Fax 508-357-7490

Hyperprolactinemia: Like other drugs that antagonize dopamine D_2 receptors, LATUDA can elevate prolactin levels, and the elevation can persist during chronic administration. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds.
In short-term placebo-controlled studies, the median change from baseline to endpoint in prolactin levels for LATUDA-treated patients was 1.1 ng/mL and was -0.6 ng/mL in the placebo-treated patients. The increase in prolactin was greater in female patients. In the longer-term studies (primarily open-label extension studies), LATUDA was associated with a median change in prolactin of -1.9 ng/mL at week 24 (n = 188), -5.4 ng/mL at week 36 (n=189) and -3.3 ng/mL at week 52 (n = 243).

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

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.

Potential for Cognitive and Motor Impairment: Somnolence and sedation were reported in patients treated with LATUDA. Patients should be cautioned about performing activities requiring mental alertness, such as operating hazardous machinery or operating a motor vehicle, until they are reasonably certain that LATUDA therapy does not affect them adversely.

Body Temperature Regulation: 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 illnesses. Close supervision of high-risk patients should accompany drug therapy. Prescriptions for LATUDA should be written for the smallest quantity of tablets in order to reduce the risk of overdose.
Alcohol: Patients should be advised to avoid alcohol while taking LATUDA.

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

Before prescribing LATUDA, please read the full Prescribing Information, including Boxed Warning.

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.

* *Manufactured by AstraZeneca.*

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

###