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

News Release

Contact: Susan Adler
Vice President, Corporate Communications
508-481-6700
susan.adler@sunovion.com

Julissa Viana
Director, Communications
201-850-9220
julissa.viana@sunovion.com

FDA APPROVES ONCE-DAILY LATUDA® (lurasidone HCl) FOR THE TREATMENT OF PATIENTS WITH SCHIZOPHRENIA

Four Positive Placebo-Controlled Trials Confirmed the Efficacy of LATUDA

Marlborough, Mass., October 28, 2010 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that the U.S. Food and Drug Administration (FDA) has approved LATUDA® (lurasidone HCl) tablets for the treatment of schizophrenia. LATUDA is an oral, once-daily atypical antipsychotic, offering a first-line treatment option for patients with schizophrenia and is expected to be available in the U.S. during the first quarter of 2011.

"LATUDA marks both a significant achievement for our company as well as the first FDA approval for Sunovion since becoming the U.S. subsidiary of Dainippon Sumitomo Pharma Co., Ltd.," said Masayo Tada, president and chief executive officer, Dainippon Sumitomo Pharma Co., Ltd. "With this approval, we've taken another big step towards becoming a truly competitive global company by enhancing the presence of Sunovion in the United States."

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.

"LATUDA offers a once-daily treatment option that has been shown to be both effective and tolerable, adding to psychiatrists' ability to address the challenging therapeutic needs of people with schizophrenia," said Antony Loebel, M.D., executive vice president, Clinical Research and Medical Affairs at Sunovion Pharmaceuticals Inc.

The FDA reviewed data from more than 40 clinical trials involving approximately 2,700 LATUDA-treated adult subjects. The efficacy of LATUDA for the treatment of schizophrenia was established in four pivotal, 6-week placebo-controlled clinical trials. In these studies, LATUDA demonstrated significantly greater improvement versus placebo on the primary efficacy measures [the Positive

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

and Negative Syndrome Scale (PANSS) total score and the Brief Psychiatric Rating Scale-derived from PANSS (BPRSd)] at study endpoint. A total of five clinical trials contributed to the understanding of the tolerability and safety profile of LATUDA.

"Schizophrenia is associated with severe and debilitating symptoms such as delusions, hallucinations and disorganized thinking, and it can often have a devastating impact on patients and their families," said Herbert Meltzer, M.D., professor of psychiatry and pharmacology, Vanderbilt University School of Medicine. "Based on the results of the clinical trials, LATUDA represents an important addition to the treatment of schizophrenia."

About LATUDA

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.

Please read the full Prescribing Information at www.LATUDA.com, including Boxed Warning.

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.

IMPORTANT SAFETY INFORMATION FOR LATUDA

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

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

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, 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 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.

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 The proportion of patients with prolactin elevations ≥ 5× ULN was 3.6% for LATUDA-treated patients versus 0.7% for placebo-treated patients. This proportion 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.

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

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, eg, 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: Given the primary CNS effects of LATUDA, caution should be used when it is taken in combination with alcohol.
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 at www.LATUDA.com, 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.

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

###