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

News Release

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

Latuda® (lurasidone HCl) Label Updated With Expanded Dosing Range Providing Added Flexibility for the Treatment of Patients with Schizophrenia

Marlborough, Mass., May 5, 2012 – Sunovion Pharmaceuticals Inc. today announced that the U.S. Food and Drug Administration (FDA) has approved an expanded dose range for LATUDA in the treatment of adult patients with schizophrenia. The FDA decision followed a review of the supplemental New Drug Application (sNDA), which was submitted in June 2011.

The maximum recommended dose of LATUDA was increased from 80 mg/day to 160 mg/day based in part on data from a 6-week placebo and active-controlled trial (N=482) involving two fixed doses of LATUDA (80 mg/day or 160 mg/day) and an active control (quetiapine XR 600 mg/day). In this study[1], both LATUDA doses demonstrated statistically significant improvement at the Week 6 study endpoint compared to placebo in change from baseline in Positive and Negative Syndrome Scale total score (PANSS, primary efficacy endpoint) and the Clinical Global Impression-Severity scale (CGI-S, key secondary efficacy endpoint). The active control (quetiapine XR) also separated from placebo on the PANSS total and CGI-S scale at study endpoint. The LATUDA safety profile in this study was consistent with prior studies in patients with schizophrenia; no new safety concerns were identified.

The newly expanded recommended dose range for LATUDA (40-160 mg/day) includes approval of the 120 mg/day and 160 mg/day doses, as well as a new 120 mg tablet. This dose range reflects positive results from five short-term studies that evaluated the safety and efficacy of LATUDA where doses of 40 mg/day, 80 mg/day, 120 mg/day and 160 mg/day were shown to be safe and effective.

"Schizophrenia is a complex disorder that requires a careful assessment of each patient. Having added dosing flexibility for LATUDA will allow physicians to better tailor treatment to the individual needs of patients with schizophrenia," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer of Sunovion Pharmaceuticals Inc.

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[1] 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. 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, quetiapine XR 600 mg/day or placebo.

The sNDA summarized safety information derived from a clinical study database consisting of 2,905 patients with schizophrenia who were exposed to at least one dose of LATUDA. Of these patients, 1,508 participated in short-term, placebo-controlled schizophrenia studies with doses of 20 mg, 40 mg, 80 mg, 120 mg or 160 mg once daily. The most common adverse reactions (incidence ≥ 5% and at least twice the rate of placebo) in patients treated with LATUDA were somnolence, akathisia, nausea and parkinsonism. There were no dose-related adverse reactions observed in patients treated with LATUDA across the 20 mg to 160 mg/day dose range compared to placebo. The frequency of akathisia increased with the dosage strength up to 120 mg/day (5.6% for LATUDA 20 mg/day, 10.7% for LATUDA 40 mg/day, 12.3% for LATUDA 80 mg/day, 22.0% for LATUDA 120 mg/day, 7.4% for LATUDA 160 mg/day and 3.0% for patients receiving placebo).

LATUDA initially received FDA approval for the treatment of schizophrenia on October 28, 2010 and is available in pharmacies across the United States and Puerto Rico.

About LATUDA
LATUDA is an atypical antipsychotic indicated for the treatment of patients with schizophrenia. Efficacy was established 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 recommended starting dose for LATUDA is 40 mg once daily taken with food (at least 350 calories) with no initial dose titration required. LATUDA has been shown to be effective in a dose range of 40 mg/day to 160 mg/day. The maximum recommended dose is 160 mg/day. For patients with moderate and severe renal or hepatic impairment, the recommended starting dose of LATUDA is 20 mg/day. The maximum recommended dose is 80 mg/day in patients with moderate hepatic impairment and 40 mg/day in patients with severe hepatic impairment. The recommended starting dose of LATUDA in patients taking a moderate CYP3A4 inhibitor such as diltiazem is 20 mg/day with a maximum recommended dose of 80 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

See full prescribing information for complete boxed warning.

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.**
- **LATUDA is not approved for the treatment of patients with dementia-related psychosis.**

CONTRAINDICATIONS

LATUDA is contraindicated in the following:

- Any patient with a known hypersensitivity to lurasidone HCl or any components in the formulation. Angioedema has been observed with lurasidone.
- Concomitant use with strong CYP3A4 inhibitors (e.g., ketoconazole)
- Concomitant use with 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 median change from baseline to endpoint in prolactin levels for LATUDA-treated females was -0.2 ng/mL and was 0.5 ng/mL for males. The proportion of female patients with prolactin elevations ≥5x ULN was 5.7% for LATUDA-treated patients versus 2.0% for placebo-treated female patients. The proportion of male patients with prolactin elevations > 5x ULN was 1.6% 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. Orthostatic vital signs should be monitored in patients who are vulnerable to hypotension and in patients with known cardiovascular disease or cerebrovascular disease.

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 17.0% (256/1508) of patients treated with LATUDA compared to 7.1% (50/708) of placebo patients, respectively. 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 and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia.

ADVERSE REACTIONS
Commonly Observed Adverse Reactions: (incidence ≥ 5% and at least twice the rate of placebo) in patients treated with LATUDA were somnolence, akathisia, nausea and parkinsonism.

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® (lurasidone HCl) tablets, LUNESTA® (eszopiclone) tablets, XOPENEX® (levalbuterol HCl) inhalation solution, XOPENEX HFA® (levalbuterol tartrate) inhalation aerosol, BROVANA® (aformoterol tartrate) inhalation solution, OMNARIS® (ciclesonide) nasal spray and ALVESCO® (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.

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