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News Release

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Sunovion Pharmaceuticals Files Two Supplemental New Drug Applications Seeking Approval for the use of Latuda® (lurasidone HCl) as Monotherapy and Adjunctive Therapy in Adult Patients with Depressive Episodes Associated with Bipolar I Disorder

Marlborough, Mass., September 6, 2012 – Sunovion Pharmaceuticals Inc. today announced that it has submitted two supplemental New Drug Applications (sNDAs) to the U.S. Food and Drug Administration (FDA) seeking approval for the use of LATUDA (lurasidone HCl) as 1) monotherapy and 2) adjunctive therapy to lithium or valproate, both to treat adult patients with depressive episodes associated with bipolar I disorder (bipolar depression). These sNDAs are supported by two 6-week, double-blind, placebo-controlled Phase 3 clinical trials, PREVAIL 1 and PREVAIL 2 (**PR**ogram to **EV**aluate the **A**ntidepressant **I**mpact of **L**urasidone), involving 852 patients with bipolar depression.

"If LATUDA is approved both for monotherapy and for adjunctive therapy of bipolar depression, it will be a first for the atypical class of drugs," said Hiroshi Nomura, Vice Chair of Sunovion Pharmaceuticals Inc. "The PREVAIL program demonstrates the company's continued commitment to the development of new treatments for people living with serious mental illness."

The two 6-week, double-blind, randomized, placebo-controlled PREVAIL trials were designed to evaluate the efficacy and safety of LATUDA as monotherapy (PREVAIL 2) and adjunctive therapy to lithium and valproate (PREVAIL 1), respectively, in adult patients with bipolar depression. Results from these studies were previously presented at the 165th Annual Meeting of the American Psychiatric Association in Philadelphia, Pennsylvania in May 2012.

"Bipolar depression is a severely debilitating illness that disrupts the lives of many patients, yet there are currently few treatment options that have successfully demonstrated efficacy in clinical trials," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer, Sunovion Pharmaceuticals Inc. "The results from the PREVAIL 1 and PREVAIL 2 studies suggest that LATUDA may be a useful treatment option for adult patients with bipolar depression."

LATUDA is not approved by the FDA for the treatment of adult patients with depressive episodes associated with bipolar I disorder. LATUDA is approved for use only in the U.S. and Canada and only for

the treatment of adult patients with schizophrenia. The safety and efficacy of LATUDA has not been reviewed by the FDA for indications other than schizophrenia.

About Bipolar I Disorder and Bipolar Depression

Bipolar disorder, a severe mental illness characterized by debilitating mood swings, affects approximately 5.7 million American adults.[1, 2] Bipolar depression refers to the depressive phase of bipolar disorder.[1] Symptoms of bipolar depression include: extreme sadness, anxiety, fatigue, inactivity and disinterest in usual activities, disruptions to sleeping patterns and hopelessness.[1, 3] When symptomatic, most people with bipolar disorder tend to be depressed, rather than manic.[4] Bipolar disorder can also double a person's risk of early death from a range of medical conditions, including obesity, diabetes and cardiovascular disease.[5, 6, 7] Worldwide, bipolar disorder is the sixth leading cause of disability.[8]

About LATUDA

LATUDA received FDA approval for the treatment of adult patients with schizophrenia on October 28, 2010.

LATUDA is an atypical antipsychotic agent indicated for the treatment of patients with schizophrenia. Efficacy was established in four six-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 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 areas of the central nervous system (CNS) and respiratory illnesses to 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), LUNESTA® (eszopiclone), 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) 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, visit Sunovion's web site at www.sunovion.com

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