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News Release

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New Study Shows Patients Can Effectively be Switched to Latuda® (lurasidone HCl) from Other Antipsychotic Agents

Data Presented at the 165th Annual Meeting of the American Psychiatric Association

Marlborough, Mass., May 9, 2012 – Sunovion Pharmaceuticals Inc. today announced results from an open-label study that switched clinically stable, but symptomatic adult outpatients with schizophrenia from other antipsychotic agents to LATUDA (lurasidone HCl) . These data were presented at the 165th Annual Meeting of the American Psychiatric Association in Philadelphia, Pennsylvania.

This 6-week open-label study included 244 patients who were clinically stable for at least eight weeks prior to the start of the study and had been on stable doses of other antipsychotic agents for at least four weeks. The study's primary endpoint was time to treatment failure (defined as discontinuation due to insufficient clinical response or an adverse event, including exacerbation of underlying disease). In addition, the study was intended to assess the safety and tolerability of switching patients from other antipsychotic agents to LATUDA.

Eligible patients were randomized to one of three LATUDA dosing regimens for the initial two weeks of the study: 1) 40 mg/day for two weeks; 2) 40 mg/day for one week, then an increase to 80 mg/day on Day 8 for Week 2 (uptitration group); and 3) 80 mg/day for two weeks. LATUDA was then flexibly dosed (40-120 mg/day) for the subsequent four weeks of the study across each of the three dosing regimens. The pre-switch antipsychotic agent was tapered by Day 7 to 50% of the original dose and discontinued by the end of Week 2.

The proportion of patients across all LATUDA doses (19/240, 7.9%) that met pre-specified criteria for treatment failure (based on initial randomized dose groups) was as follows:

- LATUDA 40 mg/day: 6.9% (5/72)
- LATUDA 40/80 mg/day (uptitration group): 9.2% (8/87)
- LATUDA 80 mg/day: 7.4% (6/81)

The overall discontinuation rate was 18.9%, with 1.2% of patients discontinuing treatment due to insufficient clinical response and 6.6% due to adverse events.

For patients who were taking concomitant antidepressants, mood stabilizers or antipsychotics at study initiation, approximately half (49.5%) of these patients discontinued use of the concomitant agent by study termination.

Adverse events (at least 5% in all LATUDA doses) observed in this study included nausea, insomnia, akathisia, headache, vomiting, somnolence and dry mouth. Results for all LATUDA-treated patients were as follows:

- Change from baseline at Week 6 LOCF endpoint:
    - Weight*: -0.7 lbs (n=220)
    - Cholesterol†: -1.0 mg/dL (n=219)
    - Triglycerides†: -6.0 mg/dL (n=219)
    - Glucose†: -1.0 mg/dL (n=219)
    - Prolactin†: +0.5 (n=219)

* Mean
† Median

Additional data showed that LATUDA-treated patients experienced improvements as assessed by the Positive and Negative Syndrome Scale total (PANSS, -5.8), Clinical Global Impression-Severity scale (CGI-S, -0.3) and the Calgary Depression Scale for Schizophrenia (CDSS, -1.3). These results were based on changes from baseline for LATUDA-treated patients; there was no placebo or other comparator. Results were similar for all three switch strategies.

"An important measure of the acceptability of any antipsychotic agent is how many people are taking it six weeks later," said Joseph McEvoy, M.D., Professor of Psychiatry and Behavioral Sciences at Duke University Medical Center. "The completion rate was notable in this study of LATUDA, with more than 80% of patients making it to six weeks. And when patients did discontinue, only 1% did so due to insufficient clinical response."

"Schizophrenia is a complex disorder whose treatment often requires switching antipsychotic agents," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer of Sunovion Pharmaceuticals Inc. "We designed this study to help physicians understand how they could switch patients to LATUDA in a real-world setting."

Overall, these findings indicate that switching to LATUDA initiated at therapeutic doses of 40 or 80 mg/day, or uptitrated from 40 mg/day to 80 mg/day, was comparably well-tolerated and effective. In addition, taper and discontinuation of the pre-switch antipsychotic agent over a two-week period was safe and well-tolerated. Since the results of switching to LATUDA were similar for the three initial dose groups, the choice of specific switch strategy may be based on individual need and clinical judgment.

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.

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® brand lurasidone HCl, LUNESTA® brand eszopiclone, XOPENEX® brand levalbuterol HCl Inhalation Solution, XOPENEX HFA® brand levalbuterol tartrate inhalation aerosol, BROVANA® brand arformoterol 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.

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