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Dainippon Sumitomo Pharma Co. Reports that Latuda® (lurasidone HCl) Met Primary and Key Secondary Endpoints in Two Phase III Trials in Bipolar I Depression

Dainippon Sumitomo Pharma Co., Ltd. (DSP) announced today results from two Phase 3 clinical trials designed to evaluate the efficacy and safety of LATUDA as adjunctive therapy and monotherapy, respectively, in patients with bipolar I depression (PREVAIL 1 and PREVAIL 2; **PR**ogram to **EV**aluate the **A**ntidepressant **I**mpact of **L**urasidone). On an overall basis in both studies, patients with bipolar I depression treated with LATUDA experienced statistically significant improvements in symptoms of depression, as measured by the Montgomery-Asberg Depression Rating Scale (MADRS), compared to patients taking placebo. In both trials, on an overall basis, patients in the LATUDA treatment arms experienced low changes in weight, lipids and measures of glycemic control.

"We believe these data show LATUDA may help patients with bipolar I depression," said Masayo Tada, Representative Director, President and Chief Executive Officer, Dainippon Sumitomo Pharma Co., Ltd. "With both studies meeting their primary endpoints, we remain on track to submit a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for LATUDA in bipolar I depression by the end of 2012."

"Bipolar I depression is highly debilitating for many patients, " said Gary Sachs, M.D., Founding Director of the Bipolar Clinic and Research Program at Massachusetts General Hospital in Boston, Massachusetts in the United States. "The efficacy and adverse effect data obtained in these studies suggest LATUDA may be a useful treatment option for patients with bipolar I depression."

LATUDA is not approved by the FDA for the treatment of bipolar disorder, including bipolar I depression. LATUDA is only approved by the FDA in the U.S. for the treatment of adult patients with schizophrenia. The safety and efficacy of LATUDA has not yet been established in bipolar I depression. The use of LATUDA outside its approved indication in the PREVAIL 1 and PREVAIL 2 studies has been carefully controlled and monitored to better understand the potential benefits and risks of the compound in the treatment of bipolar I depression. A number of factors, including the FDA regulatory review process, impact whether or not a drug product or indication will ultimately be commercialized in the U.S. Given these uncertainties, there can be no assurances that LATUDA will become commercially available for bipolar I depression in the U.S., or for any additional indications anywhere in the world.

Study Design

The objective of PREVAIL 1 was to evaluate the efficacy and safety of LATUDA when added to either lithium or valproate, two commonly used mood stabilizers. Patients who met Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) criteria for bipolar I depression and remained symptomatic (i.e., MADRS score of at least 20) following at least four weeks of treatment with either lithium or valproate were randomized to six weeks of double-blind treatment with either LATUDA 20-120 mg/day (N=183) or placebo (N=165), both adjunctive to either lithium or valproate.

The objective of PREVAIL 2 was to evaluate the efficacy and safety of LATUDA as monotherapy in patients with bipolar I depression. Patients who met DSM-IV-TR criteria for bipolar I depression and remained symptomatic (i.e., MADRS score of at least 20) were randomized to six weeks of double-blind treatment with LATUDA 20-60 mg/day (N=166), LATUDA 80-120 mg/day (N=169), or placebo (N=170).

In both studies, the pre-specified primary endpoint was change from baseline in the MADRS total score at Week 6 study endpoint. The key secondary endpoint was change from baseline in the Clinical Global Impression Bipolar Version, Severity of Illness (CGI-BP-S) score at Week 6. Changes from baseline in MADRS and CGI-BP-S were analyzed using mixed model repeated measures (MMRM); other secondary efficacy endpoints were analyzed using either MMRM or ANCOVA (LOCF).

Results from PREVAIL 1 and PREVAIL 2

Primary analyses in both studies showed treatment with LATUDA was associated with statistically significant reductions in MADRS scores at the end of each study (Week 6) compared to placebo, with this impact observed as early as Week 2 of treatment. Similarly, across both studies, LATUDA was also associated with:

- Statistically significant reductions in CGI-BP-S scores vs. placebo with improvements seen as early as Week 1.
- Statistically significantly higher responder rates (at least 50% reduction in MADRS from baseline for LATUDA) compared to placebo.
- Statistically significant reductions compared to placebo in anxiety symptoms assessed by the Hamilton Anxiety Rating Scale (HAM-A) total score.
- Statistically significant improvements in social or occupational functioning assessed by the Sheehan Disability Scale (SDS) and in quality of life, assessed by the Quality of Life, Enjoyment and Satisfaction Questionnaire (Q-LES-Q-SF).

In PREVAIL 1, the most frequently reported adverse events (≥5% in LATUDA group) were nausea (17.5% vs. 11.0%), headache (10.4% vs. 12.3%), somnolence (8.7% vs. 4.3%), tremor (8.2% vs. 4.3%), akathisia (7.7% vs. 4.3%) and insomnia (7.1% vs. 5.5%) for LATUDA vs. placebo, respectively. Discontinuation rates due to adverse events were 6% for LATUDA and 8% for placebo.

In PREVAIL 2, the most frequently reported adverse events (≥5% in either LATUDA group) were nausea (10.4%, 17.4% vs. 7.7%), headache (14.0%, 9.0% vs. 11.9%), akathisia (7.9%, 10.8% vs. 2.4%), insomnia (4.9%, 6.6% vs. 8.3%), somnolence (4.3%, 6.6% vs. 4.2%) and sedation (3.0%, 7.2% vs. 1.8%) for the LATUDA 20-60 mg/day and 80-120 mg/day dose groups vs. placebo, respectively. Discontinuation rates due to adverse events were 6% for LATUDA (either dose group) vs. 6% for placebo.

“The consistency of findings across these studies is noteworthy, suggesting that LATUDA may prove to be a viable adjunctive or monotherapy treatment alternative for patients with bipolar I depression,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer of Sunovion Pharmaceuticals Inc.

The PREVAIL program consists of three placebo-controlled studies and an open-label extension; the third placebo-controlled trial is nearing completion. This Phase 3 development program was designed to evaluate the efficacy and safety of LATUDA for the treatment of bipolar I depression.

Full results from both PREVAIL 1 and PREVAIL 2 studies will be presented at an upcoming scientific meeting in the U.S.

LATUDA received U.S. Food and Drug Administration (FDA) approval for the treatment of adult patients with schizophrenia on October 28, 2010.

About LATUDA

LATUDA is an atypical antipsychotic 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 for the treatment of patients with schizophrenia is 40 mg/day taken with food (at least 350 calories) with no initial dose titration required. LATUDA has been shown to be effective for the treatment of patients with schizophrenia in a dose range of 40 mg/day to 120 mg/day. In the six-week controlled trials of patients with schizophrenia, 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 for the treatment of patients with schizophrenia is 80 mg/day. For patients with moderate to severe renal or hepatic impairment, the dose of LATUDA should not exceed 40 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

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 about 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. Angioedema has been observed with lurasidone. LATUDA is contraindicated with strong CYP3A4 inhibitors (e.g., ketoconazole) and 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 increase in prolactin was greater in LATUDA-treated female patients; the median change from baseline to endpoint for females was 1.5 ng/mL and was 1.1 ng/mL in males. The increase in prolactin concentrations was dose-dependent. The proportion of female patients with prolactin elevations ≥5x ULN was 8.3% for LATUDA-treated patients versus 1% for placebo-treated female patients. The proportion of male patients with prolactin elevations > 5x ULN was 1.9% 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. LATUDA should be used with caution in patients with known cardiovascular disease (e.g., heart failure, history of myocardial infarction, ischemia, or conduction abnormalities), cerebrovascular disease, or conditions that predispose the patient to hypotension (e.g., dehydration, hypovolemia, and treatment with antihypertensive medications). Monitoring of orthostatic vital signs should be considered in all patients who are vulnerable to hypotension.

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 22.3% (224/1004) of patients treated with LATUDA compared to 9.9% (45/455) of placebo patients, respectively. The frequency of somnolence increases with dose. 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 is not indicated for the treatment of dementia-related psychosis, and should not be used in patients at risk for aspiration pneumonia.

DRUG INTERACTIONS
Drug Interactions: Given the primary CNS effects of LATUDA, caution should be used when it is taken in combination with other centrally acting drugs and alcohol.

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

Before prescribing LATUDA, please read the full Prescribing Information, including **Boxed Warning** at www.LATUDA.com.

About Bipolar I Disorder

Bipolar disorder affects approximately 5.7 million American adults, or about 2.6 percent of the U.S. population ages 18 and older in a given year.[1] Bipolar depression refers to the depressive phase of bipolar disorder, a severe mental illness characterized by debilitating mood swings.[2] Some people with bipolar I disorder experience periods of normal mood and behavior following a manic phase; however, all people will eventually experience a depressive phase.[3] Bipolar I disorder is characterized by having one or more manic or mixed episodes.[2] Symptoms of bipolar depression include: extreme sadness, anxiety, fatigue, inactivity and disinterest in usual activities, unintentional weight changes, disruptions to sleeping patterns, hopelessness, substance abuse and suicidality.[4] Bipolar disorder is the sixth leading cause of disability worldwide.[5] According to the

Depression and Bipolar Support Alliance, people with bipolar disorder spend more time "below baseline" in the depressed phase than in the manic phase. Bipolar depression is also more likely to be accompanied by disability and suicidal thoughts and behavior.[6]

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 central nervous system (CNS) field, which has been designated as the key therapeutic area and will also focus 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.

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 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) 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.

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