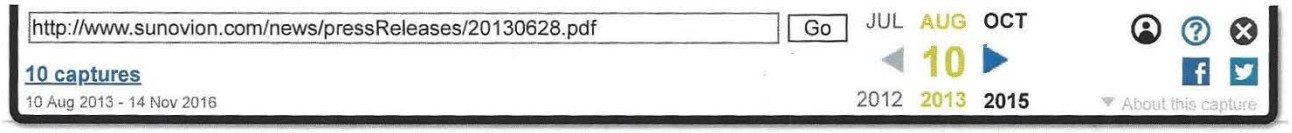

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News Release

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Sunovion Pharmaceuticals Inc. Announces FDA Approval of Latuda® (lurasidone HCl) as Monotherapy and Adjunctive Therapy in Adult Patients with Bipolar Depression

First Atypical Antipsychotic Indicated for the Treatment of Major Depressive Episodes Associated with Bipolar I Disorder (Bipolar Depression) Both as Monotherapy and as Adjunctive Therapy with Either Lithium or Valproate

Marlborough, Mass., June 28, 2013 – Sunovion Pharmaceuticals Inc. today announced that the U.S. Food and Drug Administration (FDA) approved two new indications for the use of Latuda® (lurasidone HCl) as 1) monotherapy and 2) adjunctive therapy with either lithium or valproate, both to treat adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression).[1]

"These two approvals represent a significant milestone not only for Sunovion and DSP, but for the millions of Americans who are living with bipolar disorder and struggling to manage the symptoms of bipolar depression," said Masayo Tada, Representative Director, President and Chief Executive Officer of Dainippon Sumitomo Pharma Co., Ltd. "We look forward to building on the strong foundation started in the United States to bring LATUDA to other markets around the world. In addition, we are preparing for Phase 3 clinical trials for bipolar I disorder (bipolar depression) in Japan, an important market for us, where Phase 3 clinical trials for schizophrenia are already underway. This is part of Sunovion and DSP's ongoing commitment to researching, developing and commercializing new treatments for people with mental illness."

Two positive double-blind, randomized, placebo-controlled, six-week clinical trials supported the two new indications for LATUDA for the treatment of adult patients with bipolar depression, both as monotherapy (PREVAIL 2) and as adjunctive therapy (added to background treatment with lithium or valproate) (PREVAIL 1). In both studies, the pre-specified primary endpoint was reduction in depressive symptoms, as measured by change from baseline in the Montgomery-Asberg Depression Rating Scale (MADRS) total score at Week 6. The key secondary endpoint (i.e., adjusted for multiple comparisons) was change from baseline in the Clinical Global Impression-Bipolar Version-Severity of Illness (CGI-BP-S) score at Week 6. Other secondary endpoints included changes from baseline at Week 6 in responder rates; rates of remission; Hamilton Anxiety Rating Scale (HAM-A); Sheehan Disability Scale (SDS); Quick Inventory of

Depressive Symptomatology-Self-Report (QIDS-SR_{16}); and Quality of Life, Enjoyment and Satisfaction Questionnaire-Short Form (Q-LES-Q-SF).

Both studies showed that treatment with LATUDA resulted in statistically significant reductions in MADRS scores at study endpoint compared to placebo, with significant separation from placebo observed as early as Week 2 of treatment. Additionally, across both studies, patients receiving LATUDA demonstrated statistically significant improvements vs. placebo at Week 6 on secondary endpoints, including CGI-BP-S, responder rates, rates of remission, anxiety symptoms, self-assessment of depression, as well as measures of functionality and quality and enjoyment of life.

The most common adverse reactions (incidence ≥5%, in either dose group, and at least twice the rate of placebo) in patients receiving LATUDA as monotherapy were akathisia, extrapyramidal symptoms, somnolence, nausea, vomiting, diarrhea, and anxiety; discontinuation rates due to any adverse reaction were 6.0% for LATUDA and 5.4% for placebo. In adjunctive treatment, the most common adverse reactions in patients receiving LATUDA (incidence ≥5% and at least twice the rate of placebo) were akathisia and somnolence; discontinuation rates due to any adverse reaction were 5.8% for LATUDA and 4.8% for placebo. Patients treated with LATUDA also experienced low rates of change in weight, body mass index (BMI), lipid parameters and measures of glycemic control.

"Patients with bipolar disorder spend the majority of their symptomatic time in the depressed phase of the illness. This phase most commonly results in impaired function, a remarkable decrease in quality of life and may lead to increased risk for attempted suicide," said Joseph Calabrese, M.D., Professor of Psychiatry and Director of the Mood Disorders Program at University Hospitals Case Medical Center, Case Western Reserve University. "Unfortunately, there are very few treatments specifically approved to treat the symptoms of bipolar depression, which represents a very large unmet medical need for patients and their families."

"The pharmacological profile of LATUDA, together with preclinical and initial clinical findings, suggested the potential for efficacy in depressive episodes associated with bipolar disorder. Historically, it has been difficult to show efficacy in clinical trials for the treatment of bipolar depression, but we felt strongly it was the right path to take given the high unmet need," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer of Sunovion Pharmaceuticals Inc. "We are pleased that the two new LATUDA indications for monotherapy and adjunctive treatment of bipolar depression are supported by robust evidence demonstrating efficacy and safety."

About Bipolar Depression

Bipolar disorder, a mental illness characterized by debilitating mood swings, affects approximately 10.4 million American adults.[2,3] Bipolar I disorder is characterized by at least one lifetime manic or mixed episode; often individuals have also had one or more major depressive episodes.[4] When symptomatic, most people with bipolar disorder spend more time being depressed, rather than manic.[5] Bipolar depression refers to the depressive phase of bipolar disorder.[4] Symptoms of a major depressive episode associated with bipolar depression include: depressed mood, loss of interest or pleasure in activities, significant weight loss, insomnia, fatigue, feelings of worthlessness, diminished ability to concentrate and recurrent thoughts of death or suicide attempt.[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.[6,7,8]

Bipolar disorder is the sixth leading cause of disability worldwide and is among the top 10 leading causes of disability in the United States.[9,10]

About LATUDA

LATUDA is a prescription medicine used to treat:

- Depressive episodes in bipolar I disorder in adults when used alone or with lithium or valproate
- Schizophrenia in adults

The efficacy of LATUDA in the treatment of adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression) both as 1) monotherapy and 2) adjunctive therapy with either lithium or valproate was established in one 6-week controlled monotherapy study and one 6-week controlled adjunctive study. The efficacy of LATUDA in the treatment of adult patients with schizophrenia was established in five 6-week controlled studies. 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 efficacy of LATUDA in the treatment of mania associated with bipolar disorder has not been established.

The recommended starting dose for LATUDA as monotherapy or as adjunctive therapy with either lithium or valproate for the treatment of adult patients with bipolar depression is 20 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 bipolar depression in a dose range of 20 mg/day to 120 mg/day. The maximum recommended dose for the treatment of patients with bipolar depression is 120 mg/day. In the monotherapy study, patients taking LATUDA 80 mg/day to 120 mg/day did not experience additional efficacy on average, compared to patients taking LATUDA 20 mg/day to 60 mg/day.

The recommended starting dose for LATUDA for the treatment of adult 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 160 mg/day. The maximum recommended dose for the treatment of patients with schizophrenia is 160 mg/day.

For patients with moderate to severe renal or hepatic impairment, the recommended starting dose is 20 mg/day. The dose in moderate to severe renal and moderate hepatic impairment patients should not exceed 80 mg/day and the dose in severe hepatic impairment patients should not exceed 40 mg/day. LATUDA should not be administered with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil). If LATUDA is being prescribed and a moderate CYP3A4 inhibitor (e.g., diltiazem, atazanavir, erythromycin, fluconazole, verapamil) is added to the therapy, the LATUDA dose should be reduced to half of the original dose level. If a moderate CYP3A4 inhibitor is being prescribed and LATUDA is added to therapy, the recommended starting dose of LATUDA is 20 mg/day with a maximum recommended dose of 80 mg/day. Grapefruit and grapefruit juice should be avoided in patients taking LATUDA. LATUDA should not be administered with a strong CYP3A4 inducer (e.g., rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine). If LATUDA is used concomitantly with a moderate CYP3A4 inducer, it may be necessary to increase the LATUDA dose after chronic treatment (7 days or more) with the CYP3A4 inducer.

Please see Important Safety Information, including **Boxed Warnings,** below and full Prescribing Information at www.LATUDA.com.

About Sunovion Support™

As part of its ongoing commitment to the mental health community, Sunovion Support™, the Sunovion Pharmaceuticals Inc. patient assistance program, may help eligible patients receive LATUDA at no charge to the patient. More information on this program, including eligibility criteria, may be found at www.SunovionSupport.com.

IMPORTANT SAFETY INFORMATION AND INDICATIONS FOR LATUDA

WARNINGS:

INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; AND SUICIDAL THOUGHTS AND BEHAVIORS

- **Elderly patients with dementia-related psychosis (having lost touch with reality due to confusion and memory loss) treated with this type of medicine are at an increased risk of death, compared to patients receiving placebo (sugar pill). LATUDA is not approved for treating these patients.**
- **Antidepressants have increased the risk of suicidal thoughts and actions in some children, teenagers, and young adults. Patients of all ages starting treatment should be watched closely for worsening of depression, suicidal thoughts or actions, unusual changes in behavior, agitation, and irritability. Patients, families, and caregivers should pay close attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed. Report any change in these symptoms immediately to the doctor. LATUDA is not approved for patients under the age of 18 years.**

Neuroleptic malignant syndrome (NMS): NMS is a rare and potentially fatal side effect reported with LATUDA and similar medicines. Call your doctor right away if you have high fever; stiff muscles; confusion; changes in pulse, heart rate, or blood pressure; sweating; or muscle pain and weakness. LATUDA should be stopped if you have NMS.

Tardive dyskinesia (TD): TD is a serious and sometimes permanent side effect reported with LATUDA and similar medicines. Tell your doctor about any movements you cannot control in your face, tongue, or other body parts, as they may be signs of TD. TD may not go away, even if you stop taking LATUDA. TD may also start after you stop taking LATUDA.

Metabolic Changes

High blood sugar: High blood sugar and diabetes have been reported with LATUDA and medicines like it. If you have diabetes or risk factors for diabetes, your blood sugar should be tested at the beginning of

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