

News Release

Contact: Kristina Coppola
Associate Director, Portfolio Communications
Sunovion Pharmaceuticals Inc.
508-787-4368
kristina.coppola@sunovion.com

Sunovion to Present Data Across Multiple Psychiatric Conditions at the 2017 Psych Congress

– Data include results from studies of Latuda® (lurasidone HCl) in bipolar depression and schizophrenia, and of the investigational drug dasotraline in attention deficit hyperactivity disorder (ADHD) and binge eating disorder (BED) –

Marlborough, Mass., September 14, 2017 – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) will present 10 research posters on Latuda® (lurasidone HCl) and five posters on the investigational agent dasotraline at the 30th Annual Psych Congress, which will be held September 16-19, 2017, in New Orleans, Louisiana.

LATUDA is an atypical antipsychotic agent approved in the United States for the treatment of schizophrenia in adults and adolescents (13 to 17 years of age) and for the treatment of major depressive episodes associated with bipolar I disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate in adults.

Dasotraline is a novel, dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) being investigated for the treatment of attention deficit hyperactivity disorder (ADHD) in children, adolescents and adults and binge eating disorder (BED) in adults.

“At Sunovion, we are dedicated to research and innovation in psychiatry, neurology and associated behavioral health conditions,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “Posters presented at this year’s Psych Congress reflect the continued study and development of lurasidone for both adult and pediatric patients with serious mental illness and of our investigational agent dasotraline for the treatment of patients with ADHD and binge eating disorder.”

Sunovion presentations at the Psych Congress include:

LATUDA:

- Poster 133: Exposure-Response (E-R) of Lurasidone in Pediatric Patients with Bipolar Depression: Simulation and Comparison to Adults (Sunday, September 17, 1:30 p.m. - 2:30 p.m. CDT)
- Poster 137: Efficacy and Safety of Lurasidone in Children and Adolescent Patients With Bipolar I Depression (Sunday, September 17, 1:30 p.m. - 2:30 p.m. CDT)
- Poster 142: Comparative Efficacy and Tolerability of Lurasidone versus Other Oral Atypical Antipsychotics for the Treatment of Pediatric Schizophrenia: A Network Meta-Analysis (Sunday, September 17, 1:30 p.m. - 2:30 p.m. CDT)
- Poster 147: Efficacy and Safety of Lurasidone in Bipolar Depression: Treatment Review (Sunday, September 17, 1:30 p.m. - 2:30 p.m. CDT)
- Poster 148: Efficacy of Lurasidone in Major Depressive Disorder with Mixed Features: Treatment Review (Sunday, September 17, 1:30 p.m. - 2:30 p.m. CDT)
- Poster 151: Differences in Health-related Outcomes across Antipsychotic Treatments in Patients with Schizophrenia and Bipolar Disorder (Sunday, September 17, 1:30 p.m. - 2:30 p.m. CDT)
- Poster 155: Effectiveness of Lurasidone in Adolescents with Schizophrenia: Interim Analysis at Week 52 of a 24-Month, Open-Label Extension Study (Sunday, September 17, 1:30 p.m. - 2:30 p.m. CDT)
- Poster 156: Safety of Lurasidone in Adolescents with Schizophrenia: Interim Analysis at 52 Weeks of a 24-month, Open-label Extension Study (Sunday, September 17, 1:30 p.m. - 2:30 p.m. CDT)
- Poster 224: C-Reactive Protein Effects in Patients with Bipolar Depression Treated with Lurasidone: An Exploratory Analysis of a Placebo-Controlled Trial (Sunday, September 17 and Monday, September 18, 1:30 p.m. - 2:30 p.m. CDT)
- Poster 225: Lurasidone for the Treatment of Major Depressive Disorder with Mixed Features: Do Manic Symptoms Moderate Treatment Response? (Sunday, September 17 and Monday, September 18, 1:30 p.m. - 2:30 p.m. CDT)

Dasotraline:

- Poster 213: Dasotraline in Children with Attention Deficit Hyperactivity Disorder: Results of a Randomized, Double-Blind, Placebo-Controlled Study (Sunday, September 17 and Monday, September 18, 1:30 p.m. - 2:30 p.m. CDT)
- Poster 214: Dasotraline Efficacy Throughout the Day in Children with Attention Deficit Hyperactivity Disorder: Results of a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study in a Laboratory Classroom Setting (Sunday, September 17 and Monday, September 18, 1:30 p.m. - 2:30 p.m. CDT)

- Poster 215: Dasotraline for the Treatment of Moderate-to-Severe Binge Eating Disorder in Adults: Results from a Randomized, Double-Blind, Placebo-Controlled Study (Sunday, September 17 and Monday, September 18, 1:30 p.m. - 2:30 p.m. CDT)
- Poster 315: Economic Burden of Binge Eating Disorder: Analysis of Claims from a Commercially Insured Population in the U.S. (Monday, September 18, 1:30 p.m. - 2:30 p.m. CDT)
- Poster 316: Association Between Disease Control and Healthcare Costs Among Adults with Attention Deficit Hyperactivity Disorder in the U.S.: A Retrospective Analysis of Database Claims from a Commercially Insured Population (Monday, September 18, 1:30 p.m. - 2:30 p.m. CDT)

About LATUDA

LATUDA is used to treat patients with:

- Depressive episodes in bipolar I disorder (bipolar depression) when used alone or with lithium or valproate in adults
- Schizophrenia in adults and adolescents 13 to 17 years of age

The efficacy of LATUDA was established in a 6-week placebo-controlled monotherapy study and a 6-week placebo-controlled adjunctive therapy study with lithium or valproate in adult patients with bipolar depression. The efficacy of LATUDA in schizophrenia was established in five 6-week placebo-controlled studies in adult patients and one 6-week placebo-controlled study in adolescents (13 to 17 years of age).

The most common side effects of LATUDA include sleepiness or drowsiness; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, muscle stiffness, or tremor; runny nose/nasal inflammation, and nausea.

LATUDA is available in five tablet strengths: 20 mg, 40 mg, 60 mg, 80 mg and 120 mg.

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.

Please see Important Safety Information, including BOXED WARNINGS, below and full Prescribing Information at www.LATUDA.com.

Important Safety Information and Indications for LATUDA

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

Elderly people 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 the treatment of patients with dementia-related psychosis.

Antidepressant medicines may increase suicidal thoughts or behaviors in some children, teenagers, and young adults within the first few months of treatment. Depression and other serious mental illnesses are themselves associated with an increase in the risk of suicide. Patients on antidepressants and their families or caregivers should watch for new or worsening depression symptoms, 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 use in pediatric patients with depression.

LATUDA can cause serious side effects, including stroke that can lead to death, which can happen in elderly people with dementia who take medicines like LATUDA.

Neuroleptic malignant syndrome (NMS) is a rare but very serious condition that can happen in people who take antipsychotic medicines, including LATUDA. NMS can cause death and must be treated in a hospital. Call your health care provider right away if you become severely ill and have some or all of these symptoms: high fever, excessive sweating, rigid muscles, confusion, or changes in your breathing, heartbeat or blood pressure.

Tardive dyskinesia (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.

Increases in blood sugar can happen in some people who take LATUDA. Extremely high blood sugar can lead to coma or death. If you have diabetes or risk factors for diabetes (such as being overweight or a family history of diabetes), your health care provider should check your blood sugar before you start LATUDA and during therapy. Call your health care provider if you have any of these symptoms of high blood sugar (hyperglycemia) while taking LATUDA: feel very thirsty, need to urinate more than usual, feel very hungry, feel weak or tired, feel sick to your stomach, feel confused, or your breath smells fruity.

Increases in triglycerides and LDL (bad) cholesterol and decreases in HDL (good) cholesterol have been reported with LATUDA. You may not have any symptoms, so your health care provider may decide to check your cholesterol and triglycerides during your treatment with LATUDA.

Some patients may gain weight while taking LATUDA. Your doctor should check your weight regularly.

Tell your doctor if you experience any of these:

- feeling dizzy or light-headed upon standing
- decreases in white blood cells (which can be fatal)
- trouble swallowing

LATUDA and medicines like it may raise the level of prolactin. Tell your health care provider if you experience a lack of menstrual periods, leaking or enlarged breasts, or impotence.

Tell your health care provider if you have a seizure disorder, have had seizures in the past, or have conditions that increase your risk for seizures.

Tell your health care provider if you experience prolonged, abnormal muscle spasms or contractions, which may be a sign of a condition called dystonia.

LATUDA can affect your judgment, thinking, and motor skills. You should not drive or operate hazardous machinery until you know how LATUDA affects you.

LATUDA may make you more sensitive to heat. You may have trouble cooling off. Be careful when exercising or when doing things likely to cause dehydration or make you warm.

Avoid eating grapefruit or drinking grapefruit juice while you take LATUDA since these can affect the amount of LATUDA in the blood.

Tell your health care provider about all prescription and over-the-counter medicines you are taking or plan to take, since there are some risks for drug interactions with LATUDA. Tell your health care provider if you are allergic to any of the ingredients of LATUDA or take certain medications called CYP3A4 inhibitors or inducers. Ask your health care provider if you are not sure if you are taking any of these medications.

Avoid drinking alcohol while taking LATUDA.

Tell your health care provider if you are pregnant or if you are planning to get pregnant. Avoid breastfeeding while taking LATUDA.

The most common side effects of LATUDA include sleepiness or drowsiness; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, muscle stiffness, or tremor; runny nose/nasal inflammation, and nausea.

These are not all the possible side effects of LATUDA. For more information, ask your health care provider or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

About Dasotraline

Dasotraline is a new chemical entity that acts as a dual dopamine and norepinephrine reuptake inhibitor (DNRI). It has an extended half-life (47-77 hours) that supports the potential for stable plasma concentrations yielding a continuous therapeutic effect over the 24-hour dosing interval.

Dasotraline was discovered by Sunovion Pharmaceuticals Inc. and is currently in development to evaluate its use in treating attention deficit hyperactivity disorder (ADHD) and binge eating disorder (BED). It has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of ADHD or BED.

About Schizophrenia

Schizophrenia is a chronic, serious and often severely disabling brain disorder. Symptoms such as hallucinations and delusions usually start between ages 16 and 30. Other symptoms may include unusual or dysfunctional ways of thinking, agitated body movements, reduced expression of emotions and cognitive symptoms such as poor attention, memory or executive functioning.¹

Although rare in young children, incidence of schizophrenia rises during adolescence and peaks in early adulthood. Adolescent schizophrenia is associated with poor functioning prior to the onset of illness and early developmental delays. Similar types of early developmental and social impairments have been reported in adult-onset schizophrenia, but appear to be more common and severe in adolescents.² A diagnosis of schizophrenia in adolescence may be a predictor of less independence, poorer educational achievement, lower likelihood of employment or access to further education, higher global disability scores and poor social relationships in adulthood.³

About Bipolar Disorder

Bipolar disorder is a mental health condition that is characterized by potentially debilitating mood swings, including periods of depression and mania.^{4,5} It affects approximately 12.6 million adults in the United States.^{6,7} Approximately 50 to 60 percent of adults with bipolar disorder experience their first symptoms during adolescence and it can be difficult to diagnose.^{8,9} Pediatric bipolar disorder affects approximately 1.7 percent of children and adolescents in the United States.¹⁰ Symptoms of bipolar disorder in children and adolescents can be severe and may cause young people to think about death or suicide during depressive episodes.¹¹

Bipolar disorder is the fourth leading cause of disability among children and adolescents worldwide.¹² Bipolar I disorder is characterized by at least one lifetime manic or mixed episode; individuals often have one or more depressive episodes.¹³ Bipolar depression refers to the depressive phase of bipolar disorder;¹ its symptoms 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.¹ When symptomatic, depressive symptoms affect patients more commonly than manic symptoms.¹⁴ Depressive episodes associated with bipolar disorder have been shown to result in significant impairment in work, family and social function,^{15,16} and are associated with increased risk of suicide and direct and indirect health care costs.^{17,18}

About Attention Deficit Hyperactivity Disorder (ADHD)

Attention deficit hyperactivity disorder (ADHD) is a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning and development, as characterized by inattention (e.g., distractibility, forgetfulness) and/or hyperactivity and impulsivity (e.g., fidgeting, restlessness).¹⁹ Approximately 11 percent of children four to 17 years of age have been diagnosed with ADHD in the United States.²⁰ Up to 60 percent of children with ADHD continue to experience

symptoms into adulthood.²¹ It is estimated that 4.4 percent of adults between ages 18 and 44 years experience some symptoms and disabilities from ADHD in the U.S.²²

In children, ADHD is associated with social rejection and reduced school performance.²³ Children with a history of ADHD are 10 times as likely to have difficulties with friendships and can have more frequent and severe injuries than peers without ADHD.²⁴ In adults, symptoms reduce the quality of social or occupational functioning.²⁵ Studies have shown that ADHD is associated with higher levels of unemployment, and those who are employed may experience workplace impairment, reduced productivity and behavioral issues.²⁶ Adults with ADHD are also at increased risk of trauma, workplace injuries and traffic accidents, are more likely to be diagnosed with comorbid mental health conditions and have a higher incidence of separation and divorce.^{27,28,29}

About Binge Eating Disorder (BED)

Binge eating disorder (BED) is characterized by recurrent episodes of binge eating that occur at least once per week for three months. An episode of binge eating is defined as eating an abnormally large amount of food in a discrete period of time. This is typically accompanied by a sense of lack of control. Binge eating must be characterized by marked distress and at least three of the following: eating more rapidly than normal; eating until feeling uncomfortably full; eating large amounts of food when not feeling physically hungry; eating alone because of embarrassment and feeling disgusted, guilty or depressed afterwards.³⁰ The lifetime prevalence of BED among adult women and men in the United States is 3.6 percent and 2.1 percent, respectively.^{31,32}

BED typically begins in adolescence or young adulthood but can also start later.³³ BED can lead to a number of psychological and physical problems, such as social isolation, feeling bad about oneself, problems functioning at work, obesity and related medical conditions (e.g., gastroesophageal reflux disease, joint problems, heart disease, type 2 diabetes and some sleep-related breathing disorders).³⁴ It is also associated with increased health care utilization, medical morbidity and mortality.³⁵

About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion is a global biopharmaceutical company focused on the innovative application of science and medicine to help people with serious medical conditions. Sunovion's vision is to lead the way to a healthier world. The company's spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. With patients at the center of everything it does, Sunovion has charted new paths to life-transforming treatments that reflect ongoing investments in research and development and an unwavering commitment to support people with psychiatric, neurological and respiratory conditions. Sunovion's track record of discovery, development and commercialization of important therapies has included Utibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder, Brovana® (arformoterol tartrate) inhalation solution, Latuda® (lurasidone HCl) and Aptiom® (eslicarbazepine acetate).


Headquartered in Marlborough, Mass., Sunovion is an indirect, wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. Sunovion Pharmaceuticals Europe Ltd., based in London, England, and Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's web sites: www.sunovion.com, www.sunovion.eu and www.sunovion.ca. Connect with Sunovion on [Twitter](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).


About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan operating globally in major pharmaceutical markets, including Japan, the United States, China and the European Union. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 6,500 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

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