

## News Release

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### **Sunovion Data Presentations at Annual American Psychiatric Association Meeting Showcase Growing Psychiatry Franchise**

- Data demonstrate clinical benefit for Latuda® (lurasidone HCl) in bipolar disorder in children, adolescents and adults, as well as schizophrenia in adolescents -*
- Pivotal data on novel drug candidate dasotraline in adults with binge eating disorder will be presented -*

**Marlborough, Mass., May 16, 2017** – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) will present four research posters on Latuda® (lurasidone HCl) and one on novel drug candidate dasotraline at the 170<sup>th</sup> Annual Meeting of the American Psychiatric Association (APA), which will be held May 20-24, 2017, in San Diego, California.

LATUDA is an atypical antipsychotic agent approved in the U.S. 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 and for the treatment of schizophrenia in adults and adolescents (13 to 17 years of age).

Dasotraline is a dopamine and norepinephrine reuptake inhibitor (DNRI) currently in development to evaluate its use in treating attention deficit hyperactivity disorder (ADHD) and binge eating disorder (BED).

“At Sunovion, we maintain our unwavering commitment to innovation in psychiatry, driven by awareness of the significant medical needs that exist for individuals, their families and communities,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “The data being presented on LATUDA and dasotraline are encouraging for patients and their families who are living with challenging psychiatric illnesses that may be difficult to treat.”

Key data from multiple studies for LATUDA demonstrate meaningful clinical benefit and that the treatment was well tolerated in adults, children and adolescents (10 to 17 years of age) with bipolar depression and adolescents (13 to 17 years of age) with schizophrenia.

New data presented for the first time on novel drug candidate dasotraline showed statistically significant and clinically meaningful reductions in the frequency and severity of binge eating and that dasotraline was generally well tolerated.

Sunovion presentations at APA include:

#### **LATUDA:**

- Poster P5-036: Efficacy and Safety of Lurasidone in Children and Adolescent Patients with Bipolar I Depression (Monday, May 22, 10 a.m. – 12 p.m. PDT)
- Poster P5-051: Effectiveness of Lurasidone in Adolescents with Schizophrenia: Interim Analysis of a 24-Month, Open-Label Study (Monday, May 22, 10 a.m. – 12 p.m. PDT)
- Poster P5-053: Safety of Lurasidone in Adolescents with Schizophrenia: Interim Analysis of a 24-Month, Open-Label Extension Study (Monday, May 22, 10 a.m. – 12 p.m. PDT)
- Poster P5-035: Early vs. Later Treatment Response in Lurasidone-Treated Patients with Bipolar Depression: Association with Patient-Reported Health Outcomes (Monday, May 22, 10 a.m. – 12 p.m. PDT)

#### **Dasotraline:**

- Poster P7-084: Dasotraline for the Treatment of Moderate to Severe Binge Eating Disorder in Adults: Results from a Randomized, Double-Blind, Placebo-Controlled Study (Tuesday, May 23, 10 a.m. – 12 p.m. PDT)

#### **About LATUDA**

LATUDA is approved in the U.S. for the treatment of:

- 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 monotherapy study and a 6-week 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 controlled studies in adult patients and one 6-week placebo-controlled study in adolescents (13 to 17 years).

The most common side effects associated with LATUDA include sleepiness or drowsiness; restlessness or feeling the 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](http://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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

### **About Bipolar Disorder**

Bipolar disorder is a mental health condition that is characterized by potentially debilitating mood swings, including periods of depression and mania.<sup>1,2</sup> It affects approximately 12.6 million adults in the United States.<sup>3,4</sup> Approximately 50 to 60 percent of adults with bipolar disorder experience their first symptoms during adolescence and it can be difficult to diagnose.<sup>5,6</sup> Pediatric bipolar disorder affects approximately 1.7 percent of children and adolescents in the United States.<sup>7</sup> 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.<sup>8</sup>

Bipolar disorder is the fourth leading cause of disability among children and adolescents worldwide.<sup>9</sup> Bipolar I disorder is characterized by at least one lifetime manic or mixed episode; individuals often have one or more depressive episodes.<sup>10</sup> Bipolar depression refers to the depressive phase of bipolar disorder;<sup>1</sup> 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.<sup>1</sup> When symptomatic, depressive symptoms affect patients more commonly than manic symptoms.<sup>11</sup> Depressive episodes associated with bipolar disorder have been shown to result in significant impairment in work, family and social function,<sup>12,13</sup> and are associated with increased risk of suicide and direct and indirect health care costs.<sup>14,15</sup>

### **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.<sup>7</sup> Other symptoms may include

unusual or dysfunctional ways of thinking, agitated body movements, reduced expression of emotions and cognitive symptoms such as poor focus, memory or executive functioning.<sup>7</sup>

Although rare in young children, incidence of schizophrenia rises during adolescence and peaks in early adulthood.<sup>2</sup> Adolescent schizophrenia is associated with poor functioning prior to the onset of illness and early developmental delays.<sup>2</sup> 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.<sup>2</sup> 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.<sup>8</sup>

### **About Dasotraline**

Dasotraline is a new chemical entity that is considered to be a dopamine and norepinephrine reuptake inhibitor (DNRI). It has an extended half-life (47-77 hours) that supports the potential for plasma concentrations yielding a continuous therapeutic effect over the 24-hour dosing interval. Dasotraline has shown a lower potential for abuse than methylphenidate in clinical testing.<sup>16</sup> 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, BED or any other disorder.

### **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.<sup>17</sup> The lifetime prevalence of BED among adult women and men in the United States is 3.6 percent and 2.1 percent, respectively.<sup>18,19</sup>

BED typically begins in adolescence or young adulthood but can also start later.<sup>20</sup> 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).<sup>21</sup> It is also associated with increased health care utilization, medical morbidity and mortality.<sup>22</sup>

### **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, Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, and Sunovion CNS Development Canada ULC, based in Toronto, Ontario, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's web sites: [www.sunovion.com](http://www.sunovion.com), [www.sunovion.eu](http://www.sunovion.eu) and [www.sunovion.ca](http://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](http://www.ds-pharma.com).

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