Sunovion Highlights Data from Its Psychiatry Portfolio at the 2019 American Psychiatric Association Annual Meeting

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MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion Pharmaceuticals Inc. (Sunovion) today announced that it will present clinical and health economic outcomes data from its psychiatry portfolio and pipeline of potential medicines for patients living with schizophrenia, bipolar depression and binge eating disorder, at the 2019 American Psychiatric Association (APA 2019) Annual Meeting, which will be held May 18-22, in San Francisco, Calif.

“Sunovion's presentations at APA this year include further medical insights into the long-term safety and efficacy of LATUDA for children and adolescents living with bipolar depression, data on the safety and efficacy of dasotraline for the treatment of binge eating disorder and feature exciting data on our novel investigational medicine SEP-363856 in adults with schizophrenia,” said Robert Goldman, Ph.D., Head, Global Clinical Research & Medical Affairs, at Sunovion. “In addition to this year's APA presentations, we expect to see significant advancements within Sunovion's psychiatry portfolio this year, and we look forward to sharing our progress.”

Latuda® (lurasidone HCI) is approved in the U.S. for the treatment of major depressive episodes associated with bipolar I disorder (bipolar depression) as monotherapy in adults and pediatric patients (10 to 17 years of age), bipolar depression in adults as adjunctive therapy with lithium or valproate and schizophrenia in adults and adolescents (13 to 17 years of age).

SEP-363856 is a novel agent being investigated for the treatment of patients with schizophrenia. The Phase 3 program for SEP-363856 is expected to be initiated in FY2019 (April 1, 2019 – March 31, 2020). SEP-363856 offers a novel mechanism of action that has the potential to be the first agent for the treatment of schizophrenia that is not a dopamine 2 (D2) receptor antagonist.

Sunovion presentations at APA 2019 include:

Schizophrenia

• Poster #P7-066: Efficacy and Safety of SEP-363856 in the Treatment of Schizophrenia: A Four-Week, Randomized, Placebo-Controlled Trial of a Novel Compound with a Non-D2 Mechanism of Action (Tuesday, May 21, 10:00 a.m. – 12:00 p.m. PT)

Bipolar Depression

• Poster #P8-087: Efficacy and Safety of Lurasidone in Children and Adolescents with Bipolar Depression: Results from a Two-Year, Open-Label Extension Study (Tuesday, May 21, 2:00 – 4:00 p.m. PT)

Binge Eating Disorder

• Poster #P7-090: Efficacy and Safety of Dasotraline in Adults with Binge Eating Disorder: A Randomized, Double-blind, Fixed-Dose Trial (Tuesday, May 21, 10:00 a.m. – 12:00 p.m. PT)
• Poster #P7-079: Effect of Dasotraline on Body Weight in Patients with Binge Eating Disorder (Tuesday, May 21, 10:00 a.m. – 12:00 p.m. PT)
• Poster #P7-080: Dasotraline for Treatment of Adults with Binge Eating Disorder: Effect on Binge-Related Obsessions and Compulsions as Measured by the YBOCS-BE (Tuesday, May 21, 10:00 a.m. – 12:00 p.m. PT)
• Poster #P7-089: Patient Characteristics Associated with Binge Eating Disorder (BED): An Administrative Claims Database Study (Tuesday, May 21, 10:00 a.m. – 12:00 p.m. PT)

About LATUDA (lurasidone)

LATUDA is a prescription medicine used:

• To treat adults and adolescents (13 to 17 years of age) with schizophrenia
• Alone to treat adults, children and teenagers (10 to 17 years of age) with depressive episodes that happen with bipolar I disorder (bipolar depression)
LATUDA may cause serious side effects, including:

- With the medicine lithium or valproate to treat adults with depressive episodes that happen with bipolar I disorder (bipolar depression)

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 six 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 FOR LATUDA**

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

Increased risk of death in elderly people with dementia-related psychosis. Medicines like LATUDA can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). LATUDA is not approved for the treatment of people 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 and when the dose is changed. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. 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 may cause serious side effects, including:**

- **Stroke (cerebrovascular problems)** in elderly people with dementia-related psychosis that can lead to death
- **Neuroleptic malignant syndrome (NMS) is a serious condition that can lead to death.** Call your health care provider or go to the nearest hospital emergency room right away if you have some or all of the following signs and symptoms of NMS: high fever, increased sweating, stiff muscles, confusion, or changes in your breathing, heart rate, and blood pressure
- **Uncontrolled body movements (tardive dyskinesia).** LATUDA may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop taking LATUDA. Tardive dyskinesia may also start after you stop taking LATUDA
- **Problems with your metabolism such as:**
  - **High blood sugar (hyperglycemia) and diabetes:** 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 and during treatment with LATUDA
  - **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
- **Increased fat levels (cholesterol and triglycerides) in your blood**
- **Weight gain.** You and your health care provider should check your weight regularly during treatment with LATUDA
- **Increased prolactin levels in your blood (hyperprolactinemia).** Your health care provider may do blood tests to check your prolactin levels during treatment with LATUDA. Tell your health care provider if you have any of the following signs and symptoms of hyperprolactinemia:
  - **Females:** absence of your menstrual cycle or secretion of breast milk when you are not breastfeeding
  - **Males:** problems getting or maintaining an erection (erectile dysfunction) or enlargement of breasts (gynecomastia)
- **Low white blood cell count.** Your health care provider may do blood tests during the first few months of treatment with LATUDA
- **Decreased blood pressure (orthostatic hypotension).** You may feel light-headed or faint when you rise too quickly from a sitting or lying position
- **Falls.** LATUDA may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position (orthostatic hypotension), and can slow your thinking and motor skills, which may lead to falls that can cause fractures or other injuries
- **Seizures (convulsions)**
- **Problems controlling your body temperature so that you feel too warm.** Do not become too hot or dehydrated during treatment with LATUDA. Do not exercise too much. In hot weather, stay inside in a cool place if possible. Stay out of the sun. Do not wear too much clothing or heavy clothing. Drink plenty of water
- **Mania or hypomania (manic episodes)** in people with a history of bipolar disorder. Symptoms may include: greatly
increased energy, severe problems sleeping, racing thoughts, reckless behavior, unusually grand ideas, excessive happiness or irritability, or talking more or faster than usual

- **Difficulty swallowing**

**Do not** drive, operate heavy machinery, or do other dangerous activities until you know how LATUDA affects you. LATUDA may make you drowsy.

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

**Do not** take LATUDA if you are allergic to any of the ingredients in 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.

**Tell your health care provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LATUDA and other medicines may affect each other, causing possible serious side effects. LATUDA may affect the way other medicines work, and other medicines may affect how LATUDA works. Your health care provider can tell you if it is safe to take LATUDA with your other medicines. Do not start or stop any other medicines during treatment with LATUDA without talking to your health care provider first.

**Before taking LATUDA, tell your health care provider about all of your medical conditions, including if you:**

- have or have had heart problems or stroke
- have or have had low or high blood pressure
- have or have had diabetes or high blood sugar, or have a family history of diabetes or high blood sugar
- have or have had high levels of total cholesterol or triglycerides
- have or have had high prolactin levels
- have or have had low white blood cell count
- have or have had seizures
- have or have had kidney or liver problems
- are pregnant or plan to become pregnant. It is not known if LATUDA will harm your unborn baby. Talk to your health care provider about the risk to your unborn baby if you take LATUDA during pregnancy
  - Tell your health care provider if you become pregnant or think you are pregnant during treatment with LATUDA
  - If you become pregnant during treatment with LATUDA, talk to your health care provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or going to http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/[4]
- are breastfeeding or plan to breastfeed. It is not known if LATUDA passes into your breast milk. Talk to your health care provider about the best way to feed your baby during treatment with LATUDA

The most common side effects of LATUDA include:

- Adults with schizophrenia: sleepiness or drowsiness; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, or muscle stiffness; and nausea
- Adolescents (13 to 17 years) with schizophrenia: sleepiness or drowsiness; nausea; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, muscle stiffness, or tremor; runny nose/nasal inflammation; and vomiting
- Adults with bipolar depression: restlessness or feeling like you need to move around (akathisia); difficulty moving or slow movements; and sleepiness or drowsiness
- Children (10 to 17 years) with bipolar depression: nausea; weight gain; and problems sleeping (insomnia)

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[5] or call 1-800-FDA-1088.**

**About Bipolar Disorder**

Bipolar disorder is a chronic mental health condition that can affect individuals of all ages and is characterized by potentially debilitating severe mood swings, including periods of depression and mania.\(^1,2\) It affects approximately 12.6 million adults in the U.S.\(^3,4\) Approximately 50 to 66 percent of adults with bipolar disorder experience their first symptoms before age 18, and it can be difficult to diagnose.\(^5,6\) Bipolar disorder affects approximately 1.7 percent of the pediatric population in the U.S.\(^7\) But, that number could be even higher as bipolar disorder is often misdiagnosed.\(^8,9\) Symptoms of bipolar disorder can be severe and may result in thoughts about death or suicide during depressive episodes.\(^10\)

Bipolar disorder is the fourth leading cause of disease burden among children and adolescents worldwide.\(^11\) Bipolar I disorder is characterized by at least one lifetime manic or mixed episode; individuals often have one or more depressive episodes.\(^12\) Bipolar depression refers to the depressive phase of bipolar disorder; 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. Bipolar disorder has been shown to result in significant impairment in work, family and social function, and is associated with increased direct and indirect health care costs.

About SEP-363856

SEP-363856 is an agent with a novel, non-D2 mechanism of action. Sunovion discovered SEP-363856 in collaboration with PsychoGenics based on a mechanistic-independent approach using the in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. SEP-363856 was optimized for antipsychotic activity by Sunovion medicinal chemists based on quantitative structure-activity relationship analysis, in collaboration with PsychoGenics. SEP-363856 is jointly owned by Sunovion and PsychoGenics. Sunovion has exclusive rights to develop and commercialize SEP-363856 globally.

SEP-363856 is being studied in a global development program for schizophrenia as well as for Parkinson's disease psychosis, with additional indications under consideration. Clinical trial results to date demonstrate a predictable pharmacokinetic (PK) profile suitable for once daily use.

About Schizophrenia

Schizophrenia is a chronic, serious and often severely disabling brain disorder that affects more than 23 million people worldwide and approximately one in 100 adults (about 2.4 million people) in the United States. It is characterized by positive symptoms, such as hallucinations, delusions and disorganized thinking as well as negative symptoms, such as lack of emotion, social withdrawal, lack of spontaneity and cognitive impairment that includes problems with memory, attention and the ability to plan, organize and make decisions.

About Dasotraline

Dasotraline, a dual dopamine and norepinephrine re-uptake inhibitor, is a new chemical entity that does not cause the direct release of dopamine and norepinephrine from neuronal vesicles. It has an extended half-life (47-77 hours) that supports stable plasma concentrations over the 24-hour dosing interval with once a day dosing.

Dasotraline was discovered by Sunovion Pharmaceuticals Inc. and is being evaluated for 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 Binge Eating Disorder (BED)

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 abnormal large amount of food in a discrete period of time. This is typically accompanied by a sense of loss 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.

The lifetime prevalence of BED among adult women and men in the U.S. is 3.6 percent and 2.1 percent, respectively.

BED typically begins in young adulthood but can also start later. 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). It is also associated with increased healthcare utilization, medical morbidity and mortality.

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.


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 U.S., China and the European Union. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area, the Oncology area and Regenerative medicine/Cell therapy field, 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 6,200 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at https://www.ds-pharma.com.

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