Sunovion to Deliver Multiple Presentations at the 2018 American Psychiatric Association Annual Meeting

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Terms:

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- New data analyses highlight the use of Latuda® (lurasidone HCl) in pediatric populations, including long-term efficacy and safety outcomes in bipolar depression and schizophrenia -

- Further data on use of dasotraline in children and adults with ADHD and adults with binge eating disorder (BED) will be presented -

MARLBOROUGH, Mass.--(BUSINESS WIRE)--Sunovion will present eight posters on Latuda® (lurasidone HCl) and three posters on the investigational agent dasotraline at the 2018 American Psychiatric Association (APA) Annual Meeting, which will be held May 5-9, 2018, in New York City.

"The focus of presentations on lurasidone at this year's APA meeting will be on a range of long-term safety and effectiveness data in youth with bipolar disorder and schizophrenia. In addition, further data on the novel agent dasotraline, which is being studied for binge eating disorder and attention deficit hyperactivity disorder, will be presented," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. "These presentations reflect Sunovion's ongoing commitment to greater scientific understanding across our therapeutic areas of focus."

LATUDA® (lurasidone HCl) is approved in the U.S. for the treatment of major depressive episode 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).

Dasotraline is a novel dual-acting dopamine and norepinephrine reuptake inhibitor (DNRi) for the treatment of binge eating disorder (BED) in adults.

Sunovion presentations at the 2018 APA Annual Meeting include:

LATUDA:
- Poster #P5-030: Effectiveness of Long-term Lurasidone in Children and Adolescents with Bipolar Depression: Interim Analysis at Year One of a Two-Year Open-label Extension Study (Monday, May 7, 10:00 a.m. - 12:00 p.m. EDT, Hall 3B, Third Level, Javits Center)
- Poster #P7-045: Efficacy and Safety of Lurasidone in Adolescents with Schizophrenia: Interim Analysis of a 24-Month, Open-label Extension Study (Tuesday, May 8, 10:00 a.m. - 12:00 p.m. EDT, Hall 3B, Third Level, Javits Center)
- Poster #P7-046: Lurasidone for the Treatment of Major Depressive Disorder With Mixed Features: Results of a 12-week Open-label Extension Study (Tuesday, May 8, 10:00 a.m. - 12:00 p.m. EDT, Hall 3B, Third Level, Javits Center)
- Poster #P7-129: Inflammatory Markers and Cognitive Performance in Patients with Schizophrenia Treated with Lurasidone (Tuesday, May 8, 10:00 a.m. - 12:00 p.m. EDT, Hall 3B, Third Level, Javits Center)
- Poster #P8-203: Effect of Lurasidone on Cognition in Child and Adolescent Patients with Bipolar Depression: Interim Analysis at 1 year of a 2 year, Open-label Extension Study (Tuesday, May 8, 2:00 p.m. - 4:00 p.m. EDT, Hall 3B, Third Level, Javits Center)
- Poster #P8-204: Safety of Long-term Treatment with Lurasidone in Child and Adolescent Patients with Bipolar Depression: Interim Analysis at 1 year of a 2 year, Open-label Extension Study (Tuesday, May 8, 2:00 p.m. - 4:00 p.m. EDT, Hall 3B, Third Level, Javits Center)
- Poster #P8-207: Efficacy of Lurasidone in Child and Adolescent Patients with Bipolar Depression and Anxiety: A Post-hoc Analysis (Tuesday, May 8, 2:00 p.m. - 4:00 p.m. EDT, Hall 3B, Third Level, Javits Center)

Dasotraline:
- Poster #P7-202: Dasotraline for Treatment of Adults with Binge-Eating Disorder: Effect on Behavioral Outcomes (Tuesday, May 8, 10:00 a.m. - 12:00 p.m. EDT, Hall 3B, Third Level, Javits Center)
- Poster #P8-194: Improvement in ADHD-related Symptoms and Behaviors in Children with ADHD Treated with Dasotraline: Results of a Post-hoc ADHD-RS-V Item Analysis (Tuesday, May 8, 2:00 p.m. - 4:00 p.m. EDT, Hall 3B, Third Level, Javits Center)
- Poster #P8-198: Dasotraline for the Treatment of Attention-Deficit Hyperactivity Disorder in Adults: Pooled Analysis of Two Double-Blind Studies (Tuesday, May 8, 2:00 p.m. - 4:00 p.m. EDT, Hall 3B, Third Level, Javits Center)

About LATUDA

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)
- 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:
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. Bipolar disorder affects approximately 12.6 million adults in the U.S., approximately 50 to 66 percent of adults with bipolar disorder experience their first symptoms before age 18, and it can be difficult to diagnose. Bipolar disorder affects approximately 1.7 million children and adolescents worldwide. Bipolar disorder is characterized by at least one lifetime manic or mixed episode; individuals often have one or more depressive episodes. 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. 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 healthcare costs.

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. 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. 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.

About Dasotraline

Dasotraline is a medication that can 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:

- Weight gain, You and your healthcare provider should check your weight regularly during treatment with LATUDA.
- Increased fat levels (cholesterol and triglycerides) in your blood

Problems controlling your body temperature so that you feel too warm.

- 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 healthcare provider if you are not sure if you are taking any of these medications.
- Tell your healthcare 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 healthcare 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 healthcare provider first.

Before taking LATUDA, tell your healthcare 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 healthcare provider about the risk to your unborn baby if you take LATUDA during pregnancy
- Tell your healthcare 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 healthcare 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 healthcare 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/ocular 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 healthcare 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 Neuroleptic Malignant Syndrome

Neuroleptic malignant syndrome (NMS) is a serious condition that can lead to death. Call your healthcare 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 healthcare provider should check your blood sugar before you start and during treatment with LATUDA.
- Call your healthcare 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

Increased prolactin levels in your body (hyperprolactinemia).

- Do not take LATUDA since these can affect the amount of LATUDA in the blood.
- Tell your healthcare provider if you are pregnant or think you are pregnant during treatment with LATUDA.
- If you become pregnant during treatment with LATUDA, talk to your healthcare 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]
Dasotraline is a new chemical entity that acts as a dual dopamine and norepinephrine reuptake inhibitor (DNNR). 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 Attention Deficit Hyperactivity Disorder (ADHD)**

Attention deficit hyperactivity disorder (ADHD) is a persistent pattern of inattentiveness and motor 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). Approximately 11 percent of children four to 17 years of age have been diagnosed with ADHD in the U.S. Up to 60 percent of children with ADHD continue to experience symptoms into adulthood. It is estimated that 4.4 percent of adults between the ages of 18 and 44 experience some symptoms and disabilities from ADHD in the U.S.

In children, ADHD is associated with social rejection and reduced school performance. Children with a history of ADHD are ten times more likely to have difficulties with friendships and can have more frequent and severe injuries than peers without ADHD. In adults, symptoms reduce the quality of social or occupational functioning. 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.

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.

**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 at least to 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 adolescence or 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., gastrointestinal reflux disease, joint problems, heart disease, type 2 diabetes and some sleep-related breathing disorders). It is also associated with increased health care 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 innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. Without limits, 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 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. Sunovion Pharmaceuticals Europe Ltd. is the merged entity between Dainippon Sumitomo Pharma Ltd. and Sunovion Pharmaceuticals Co., Ltd. Today, Sunovion 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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**References**

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