



NEWS RELEASE

# Sunovion Presents Data From Marketed and Late-Stage Development Psychiatric Compounds At The American Psychiatric Association (APA) Annual Meeting 2021

5/3/2021

- An analysis compares clinical safety data of investigational agent SEP-363856 with real-world safety reports of approved antipsychotics, highlighting differentiated profile of SEP-363856 -

- New post-hoc analysis indicates treatment with Latuda® (lurasidone HCl) improved psychic and somatic anxiety in adults with bipolar depression -

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- **Sunovion Pharmaceuticals Inc.** (Sunovion) today announced data presentations on the late-stage pipeline candidate SEP-363856, a trace amine-associated receptor 1 (TAAR1) agonist with serotonin 5-HT1A agonist activity under investigation for the treatment of schizophrenia, and Latuda in bipolar depression at the American Psychiatric Association Annual Meeting, May 1-3, 2021.

The poster titled "The Safety Profile of the TAAR1 Agonist, SEP-363856, is Distinct From Atypical Antipsychotics," (poster P12-007), details a disproportionality analysis of data from the U.S. Food and Drug Administration's (FDA) real-world adverse event reporting database (FAERS), summarizing adverse events (AEs) by cumulative burden of class-specific risks. The data review compared the frequencies of antipsychotic schizophrenia treatment class-related AEs occurring in 11 atypical antipsychotics to those occurring in the SEP-363856 safety database across clinical studies. The analysis found that for SEP-363856, the cumulative rate and pattern of AEs was distinctly different compared to atypical antipsychotics generally.

“The SEP-363856 safety analysis presented at APA supports previous clinical trial evidence that this agent is associated with a differentiated side effect profile compared to currently approved atypical antipsychotics. These data further support the characterization of SEP-363856 as representing a new class of medicines for the treatment of schizophrenia,” said Armin Szegedi, MD, PhD, Senior Vice President and Chief Medical Officer of Sunovion. “We are pleased to discuss these SEP-363856 data with the clinical community to foster further understanding of this novel compound.”

Another SEP-363856 presentation titled “Effects of SEP-363856, a Novel TAAR1 Agonist, on Negative Symptoms in Schizophrenia: Results Across an Initial Double-Blind Acute Study and a 6-Month, Open-Label Extension Study,” (poster P11-086), demonstrates that short-term treatment with SEP-363856 was associated with improvement relative to placebo in negative symptoms of schizophrenia as assessed by the Brief Negative Symptom Scale (BNSS) total score and BNSS factor scores, and long-term treatment with SEP-363856 was associated with additional mean improvement from baseline to Week 26.

Additionally, the poster titled “Lurasidone in the Treatment of Comorbid Anxiety Symptoms in Bipolar Depression,” (poster P5-457), features a post-hoc analysis of pooled data from two placebo-controlled studies on lurasidone as monotherapy (20-60 mg/d and 80-120 mg/d) and as adjunctive therapy (20-120 mg/day flexibly dosed) with lithium or valproate in adult patients with bipolar depression. According to measurements from the Hamilton Anxiety Rating Scale (HAM-A), treatment with lurasidone improved psychic anxiety from baseline to Week 6 both as monotherapy (LS mean change -4.58,  $p < 0.001$  for 20-60 mg/d; LS mean change -4.40,  $p < 0.01$  for 80-120 mg/d; vs. -2.87 for placebo) and as adjunctive therapy with lithium/valproate (LS mean change -5.72 vs. -4.42 for lithium/valproate plus placebo,  $p < 0.01$ ). Lurasidone was also associated with improvement in somatic anxiety from baseline to Week 6 as adjunctive therapy with lithium/valproate (LS mean change -2.30 vs. -1.58 for lithium/valproate plus placebo,  $p < 0.01$ ). Numeric improvement in somatic anxiety was observed for lurasidone monotherapy treatment (mean change -1.89,  $p = 0.09$  for 20-60 mg/d; mean change -1.70,  $p = \text{NS}$  for 80-120 mg/d; vs. mean change -1.40 for placebo).

Additional lurasidone presentations at the APA 2021 virtual meeting include the poster titled “Subthreshold Manic Symptoms (Sleep Disturbance and Irritability) and Response to Lurasidone in Children and Adolescents with Bipolar Depression,” (poster P9-074), which suggests that sleep disturbance and irritability may be important moderators of lurasidone treatment response in children and adolescents with bipolar depression.

Sunovion also presented “Efficacy and Safety of Lurasidone in Adolescents and Young Adults with Schizophrenia: Pooled Analysis of Double-blind, Placebo-controlled 6-Week Studies,” (poster P11-098), in which lurasidone treatment was associated with a favorable efficacy and tolerability profile in adolescents and young adults with schizophrenia.

Sunovion also presented a cross-sectional survey titled, “Real-world Outcomes Associated with Cognitive Impairment Among Patients with Schizophrenia,” (poster P11-108), demonstrating that schizophrenia patients with more cognitive impairment had more hospitalizations due to relapse, and patients with severe cognitive impairment had lower quality of life and overall satisfaction with life compared to patients with mild cognitive impairment.

## IMPORTANT SAFETY INFORMATION AND INDICATIONS 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 lightheaded 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/>
- 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

## INDICATIONS

LATUDA is a prescription medicine used:

- To treat adults and adolescents (13 to 17 years) with schizophrenia
- Alone to treat adults, children and teens (10 to 17 years) 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)

## About SEP-363856

SEP-363856 is a TAAR1 agonist with 5-HT1A agonist activity that is under investigation for the treatment of schizophrenia and other CNS conditions. Sunovion discovered SEP-363856 in collaboration with PsychoGenics based in part on a mechanism-independent approach using the in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. SEP-363856 is being studied in a global Phase 3 development program for schizophrenia (DIAMOND) with additional indications under consideration. The U.S. FDA granted Breakthrough Therapy Designation for SEP-363856 for schizophrenia in May 2019. The full results of a four-week pivotal study (SEP361-201) evaluating the safety and efficacy of SEP-363856 in patients with schizophrenia were published in the [New England Journal of Medicine \(NEJM\)](#) in April 2020.

## About LATUDA (lurasidone HCl)

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 associated with bipolar I disorder (bipolar depression)
- With the medicine lithium or valproate to treat adults with depressive episodes associated 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](http://www.LATUDA.com).

## About Schizophrenia

Schizophrenia is a chronic, serious and often severely disabling brain disorder that affects more than 20 million people worldwide<sup>1</sup> and approximately 1 million people in the United States.<sup>2</sup> 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.<sup>3</sup>

## About Bipolar Disorder

Bipolar disorder affects approximately 12.6 million individuals in the United States and an estimated 29 million people worldwide.<sup>4,5</sup> A person is usually diagnosed with bipolar disorder after experiencing at least one manic episode, with symptoms that are not better explained by another mental health condition, such as schizophrenia.<sup>6</sup> Bipolar disorder is characterized by debilitating mood swings, interspersed with periods of stable mood and behavior.<sup>6</sup> When individuals with bipolar disorder are experiencing symptoms, most tend to be depressed, rather than manic.<sup>7</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.

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 websites: [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-10 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 more than 6,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at <https://www.ds-pharma.com>.

LATUDA and SUNOVION are registered trademarks of Sumitomo Dainippon Pharma Co., Ltd.

Sunovion Pharmaceuticals Inc. is a U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd.

© 2021 Sunovion Pharmaceuticals Inc. All rights reserved.

For a copy of this release, visit Sunovion's website at [www.sunovion.com](http://www.sunovion.com)

## References

---

---

<sup>1</sup>World Health Organization. Mental Disorders. [Internet]. Available from: <https://www.who.int/news-room/fact-sheets/detail/mental-disorders>. Accessed April 2021.

2National Institute of Mental Health. Schizophrenia. [Internet]. Available from: <https://www.nimh.nih.gov/health/statistics/schizophrenia.shtml>. Accessed April 2021.

3National Institute of Mental Health. Schizophrenia. [Internet]. Available from: <https://www.nimh.nih.gov/health/topics/schizophrenia/index.shtml>. Accessed March 2021.

4National Institute of Mental Health. Bipolar Disorder. [Internet]. Accessed March 17, 2016.

5“Bipolar Disorder.” Decision Resources. Table 2-2. Burlington, MA. December 2013.

6National Alliance on Mental Illness. The Impact and Cost of Mental Illness: The Case of Bipolar Disorder. [Internet]. Accessed March 17, 2016.

7The Depression and Bipolar Support Alliance. Mood Disorders and Different Kinds of Depression. [Internet]. Accessed March 17, 2016.

Kirsten Fallon  
Associate Director, Portfolio Communications  
Sunovion Pharmaceuticals Inc.  
774-369-7116  
**kirsten.fallon@sunovion.com**

Source: Sunovion Pharmaceuticals Inc.

