

News Release

Contact: Kristina Coppola
Senior Manager, Corporate Communications
Sunovion Pharmaceuticals Inc.
508-787-4368
kristina.coppola@sunovion.com

Sunovion to Present Data on LATUDA® (lurasidone HCl) at the 25th European Congress of Psychiatry

– Presentations include Phase 3 clinical trial data supporting the recent U.S. FDA approval of LATUDA for the treatment of schizophrenia in adolescents aged 13 to 17 years –

Marlborough, Mass., March 31, 2017 – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) will present two research posters and deliver two oral research presentations on LATUDA® (lurasidone HCl) at the 25th European Congress of Psychiatry (EPA 2017) to be held April 1-4, 2017, in Florence, Italy.

LATUDA was [recently approved](#) by the U.S. Food and Drug Administration (FDA) for the treatment of schizophrenia in adolescents aged 13 to 17 years. LATUDA is also approved in the U.S. for the treatment of adults with schizophrenia and for the treatment of adults with major depressive episodes associated with bipolar I disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate. LATUDA is approved in the EU for the treatment of adult patients with schizophrenia.

“We’re pleased to present data from several studies including a Phase 3 clinical trial of LATUDA in adolescents with schizophrenia that supported the first U.S. approval for this indication in five years,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “We remain committed to addressing unmet medical needs for people living with mental illness, and these presentations reflect our ongoing efforts to facilitate informed discussion of LATUDA across the global medical community.”

Other key presentations will include data on the effects of continued treatment with LATUDA in adults with bipolar depression and a post-hoc analysis examining the efficacy of LATUDA in major depressive disorder with mixed features (MDD-MF).

Sunovion data presentations include:

- Presentation O062: The Efficacy of Lurasidone on PANSS Subscales in Adolescent Patients with Schizophrenia (Monday, April 3, 15:10-15:15 CET, 9:10-9:15 a.m. ET)
- Presentation O070: The Efficacy and Safety of Lurasidone in Adolescent Patients with Schizophrenia: Results of Functional and Quality of Life Measures from a 6-Week, Double-Blind, Placebo-Controlled Study (Monday, April 3, 15:50-15:55 CET, 9:50-9:55 a.m. ET)
- Poster EW0404: Lurasidone for the Treatment of Major Depressive Disorder with Mixed Features: Do Manic Symptoms Moderate Treatment Response? (Monday, April 3, 12:30-13:15 CET, 6:30-7:15 a.m. ET)
- Poster EW0304: Lurasidone Adjunctive to Lithium or Valproate for Prevention of Recurrence in Bipolar I Disorder (Monday, April 3, 12:30-13:15 CET, 6:30-7:15 a.m. ET)

About LATUDA

LATUDA is approved in the U.S. and Canada for the treatment of adult patients with schizophrenia and for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression) as monotherapy or as adjunctive therapy with lithium or valproate. LATUDA is also approved in the U.S. for the treatment of adolescents ages 13 to 17 years with schizophrenia.

LATUDA is approved for the treatment of adult patients with schizophrenia in the EU, Switzerland, Australia, Taiwan, Russia, Singapore, Thailand and Hong Kong.

(U.S.) 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.

Please see Important Safety Information, including **Boxed Warnings**, and full Prescribing Information at www.LATUDA.com.

(EU) IMPORTANT SAFETY INFORMATION FOR LATUDA ▼

Please refer to the Summary of Product Characteristics (SmPC)

www.medicines.org.uk/emc/medicine/29125

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Adverse reactions should be reported to the Competent Authority in your country. Adverse reactions should also be reported to Sunovion Pharmaceuticals Europe Ltd. on +44207 821 2899.

About Schizophrenia

Schizophrenia is a chronic, serious and often severely disabling brain disorder that affects approximately 1 in 100 American adults (about 2.4 million people) in the United States.¹ It is characterized by symptoms such as hallucinations, delusions, disorganized thinking, lack of emotion and lack of energy, as well as problems with memory, attention and the ability to plan, organize and make decisions.²

About Bipolar Depression

Bipolar disorder, a mental health condition that requires long-term treatment and is characterized by debilitating mood swings³, affects approximately 12.6 million adults in the United States.^{4,5} It is among the top 10 leading causes of disability in the United States.^{6,7} Bipolar I disorder is characterized by at least one lifetime manic or mixed episode; often individuals have one or more depressive episodes.⁸ Bipolar depression refers to the depressive phase of bipolar disorder;³ 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.³ When symptomatic, most individuals with bipolar disorder spend more time in the depressive phase.⁹ Depressive episodes associated with bipolar disorder have been shown to result in significant impairment in work, family and social function,^{10,11} and are associated with increased risk of suicide and direct and indirect healthcare costs.^{12,13}

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 Brovana[®] (arformoterol tartrate), 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, 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.

BROVANA is a registered trademark of Sunovion Pharmaceuticals Inc.
LATUDA is a registered trademark of Sumitomo Dainippon Pharma Co., Ltd.
APTIOM is used under license from BIAL.

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

© 2017 Sunovion Pharmaceuticals Inc.

For a copy of this release, visit Sunovion's web site at www.sunovion.com

References

¹ Regier DA, Narrow WE, Rae DS, Mandercheid RW, Locke B2, Goodwin, FK. The de Facto US Mental and Addictive Disorders Service System. Arch Gen Psychiatry. 1993;50:85-94. Calculated by extrapolating from the 2008 United States Census Bureau population estimates.

² NAMI, Schizophrenia. Available at: http://www.nami.org/Template.cfm?Section=By_Illness&Template=/TaggedPage/TaggedPageDisplay.cfm&TPLID=54&ContentID=23036. Accessed May 15, 2013.

³ Swann, AC. Long-term treatment in bipolar disorder. Journal of Clinical Psychiatry. 2005; 66(1):7-12.

⁴ National Institute of Mental Health. Bipolar Disorder. [Internet]. Available from: <http://www.nimh.nih.gov/health/topics/bipolar-disorder/index.shtml>. Accessed March 17, 2016.

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

⁶ National Alliance on Mental Illness. The Impact and Cost of Mental Illness: The Case of Bipolar Disorder. [Internet]. Available from: <http://www2.nami.org/Template.cfm?Section=members&template=/ContentManagement/ContentDisplay.cfm&ContentID=42734>. Accessed March 17, 2016.

⁷ National Alliance on Mental Illness. A Primer on Depressive, Bipolar and Anxiety Illnesses: Facts for Policymakers. [Internet]. Available from: <http://www2.nami.org/walkTemplate.cfm?Section=NAMIWALKS&template=/ContentManagement/ContentDisplay.cfm&ContentID=42736>. Accessed March 17, 2016.

⁸ American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision. Washington, DC, American Psychiatric Association, 2000.

⁹ The Depression and Bipolar Support Alliance. Mood Disorders and Different Kinds of Depression. [Internet]. Available from: http://www.dbsalliance.org/site/PageServer?pagename=education_bipolar_types. Accessed March 17, 2016.

¹⁰ Huxley N, Baldessarini RJ. Disability and Its Treatment in Bipolar Disorder Patients. Bipolar Disorder. 2007; 9(1-2):183-96.

¹¹ Calabrese JR, Hirschfeld RM, Frye MA, Reed ML. Impact Of Depressive Symptoms Compared With Manic Symptoms In Bipolar Disorder: Results Of A U.S. Community-Based Sample. Journal of Clinical Psychiatry. 2004; 65(11):1499-504.

¹² Parker G, McCraw S, Hadzi-Pavlovic D, Fletcher K. Costs Of The Principal Mood Disorders: A Study Of Comparative Direct And Indirect Costs Incurred By Those With Bipolar I, Bipolar II And Unipolar Disorders. Journal of Affective Disorders. 2012; 149(1-3):46-55. (ePub).

¹³ Leverich GS, Altshuler LL, Frye MA, et al. Factors Associated With Suicide Attempts In 648 Patients With Bipolar Disorder In The Stanley Foundation Bipolar Network. Journal of Clinical Psychiatry. 2003; 64(5):506-15.