Sunovion Announces Health Canada Approval of Latuda® (lurasidone HCI) to Treat Adolescents (13 to 17 years of age) with Bipolar Depression

Release Date:
Friday, April 20, 2018 11:34 am EDT

Terms:

Dateline City:
MARLBOROUGH, Mass.

MARLBOROUGH, Mass. -- (BUSINESS WIRE) -- Sunovion Pharmaceuticals Inc., (Sunovion) today announced that Health Canada has approved the Supplemental New Drug Submission (SNDs) that expands the use of Latuda® (lurasidone HCI) to include the acute management of depressive episodes associated with bipolar disorder in adolescents (13 to 17 years of age).

LATUDA is currently indicated in Canada for the management of the manifestations of schizophrenia in adults and adolescents (15 to 17 years of age) and the acute management of depressive episodes associated with bipolar disorder in adults.

"Given the enormous burden of depression symptoms, and the high rates of suicidality among youth with bipolar disorder, there is an urgent need for treatments that are supported by gold-standard evidence," said Benjamin Goldstein, M.D., Ph.D., FRCP, Director of the Centre for Youth Bipolar Disorder at Sunnybrook Health Sciences Centre, and Professor of Psychiatry and Pharmacology at the University of Toronto, Ontario. "LATUDA is a new, effective and generally well-tolerated treatment option for adolescents with bipolar depression, and is a first-line treatment in recent international treatment guidelines. Having evidence-based treatments for bipolar depression in adolescent patients is critically important for the Canadian mental health community."

The SNDs is supported by data from a Phase 3 clinical study of children and adolescents (10 to 17 years of age) with bipolar depression. In this study, LATUDA was associated with statistically significant and clinically meaningful improvement in bipolar depression symptoms compared to placebo and was generally well-tolerated.

"This approval marks an important milestone for the mental health community in Canada, where few approved treatment options are available to adolescents with bipolar depression," said David Frawley, Executive Vice President, Chief Commercial Officer at Sunovion. "Sunovion is committed to improving the lives of people facing this serious condition, and we are proud that LATUDA can now be considered for use in Canada for adolescent patients in addition to adult patients with bipolar depression."

Phase 3 Study Results

In the six-week, randomized, double-blind, placebo-controlled study, 347 children and adolescents (10 to 17 years of age) with bipolar depression received once-daily LATUDA flexibly dosed (20-80 mgidally) or placebo. LATUDA was associated with statistically significant and clinically meaningful improvement in bipolar depression symptoms compared to placebo, based on the primary efficacy endpoint of change from baseline to Week 6 on the Children's Depression Rating Scale, Revised (CDRS-R) total score (<21.6 vs. -13.3; effect size = 0.49, p<0.0001). Statistically significant and clinically relevant change from baseline to Week 6 on the Clinical Global Impression-Bipolar Version, Severity of Illness (CGI-BP-S) score (depression) at the secondary endpoint was also seen with LATUDA compared to placebo (<1.49 vs. -1.05; effect size = 0.44, p=0.0001).

LATUDA was generally well-tolerated. The most common treatment-emergent adverse events (TEAEs) reported for LATUDA compared to placebo were nausea (16.0% vs. 5.8%), weight gain (6.9% vs. 1.7%) and insomnia (5.1% vs. 2.3%).

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 is the fourth leading cause of disease burden among children and adolescents worldwide. In Canada, more than 730,000 people aged 15 years and older report symptoms that meet the criteria for bipolar disorder.

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. Approximately 50 to 60 percent of adults with bipolar disorder experience their first symptoms before age 18, and 10 to 20 percent of children, teenagers, and young adults within the first few months of treatment and when 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.
- Seizures in some people. Contact your health care provider if you have any of the following signs and symptoms of hyperprolactinemia:
  - 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 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.
  - Contact 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, which 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

(U.S.) 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 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.

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Published on Sunovion (https://www.sunovion.com) on 4/20/2018 11:34 am EDT
- 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 taking 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 any other medicines 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.nبرgicandresearchprograms/pregnancyregistry](http://womensmentalhealth.nبرgicandresearchprograms/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: restlessness, 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.

(CANADA) Important Safety Information for LATUDA

Indications and Clinical Use:

Adults

Schizophrenia

LATUDA (lurasidone HCl) is indicated for the management of the manifestations of schizophrenia. The antipsychotic efficacy of LATUDA was established in short-term (6-week) controlled trials. The efficacy of LATUDA in long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled trials of patients with manifestations of schizophrenia.

Depressive Episodes Associated with Bipolar Disorder

LATUDA is indicated as monotherapy or as adjunctive therapy with lithium or valproate for the acute management of depressive episodes associated with bipolar disorder.

The efficacy of LATUDA for long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled studies. 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.

Geriatrics (>65 years of age):

LATUDA is not indicated in elderly patients with dementia. The safety and efficacy of LATUDA in patients 65 years of age or older has not been established.

Pediatrics (<18 years of age)

When prescribing to adolescents with schizophrenia or adolescents with depressive episodes associated with bipolar disorder, clinicians must take into account the safety concerns associated with all antipsychotic drugs, which include: extrapyramidal effects, hyperglycemia, weight gain, and hyperlipidemia, which can be more frequent or more severe in this patient population than in adults. LATUDA should only be prescribed to adolescents with schizophrenia or bipolar disorder by clinicians who are experienced in the diagnosis and treatment of adolescents with psychiatric disorders and who are experienced in the early detection and management of the above-mentioned safety issues associated with this class of drugs.

Schizophrenia

LATUDA is indicated for the management of the manifestations of schizophrenia in adolescents (15-17 years). The safety and efficacy of LATUDA was evaluated in one short-term (6-week) controlled trial in adolescents (13-17 years). LATUDA is not indicated for the treatment of schizophrenia in adolescents less than 15 years of age due to insufficient safety and efficacy data.

The efficacy of LATUDA in long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled trials of patients with manifestations of schizophrenia. The physician who elects to use LATUDA for extended periods in adolescents with manifestations of schizophrenia should periodically re-evaluate the long term usefulness of the drug for the individual patient.

The safety and efficacy of LATUDA in schizophrenia patients less than 15 years of age has not been evaluated.

Depressive Episodes Associated with Bipolar Disorder

LATUDA is indicated as monotherapy for the acute management of depressive episodes associated with bipolar disorder in adolescent (13 to 17 years) patients. The safety and efficacy of LATUDA 20 to 80 mg/day for the treatment of bipolar depression in children and adolescents (10 to 17 years) was evaluated in a 6-week, placebo-controlled clinical study in 343 children and adolescents. LATUDA is not indicated for the treatment of depressive episodes in bipolar disorder in patients less than 13 years of age due to insufficient safety and efficacy data.

Most serious warnings and precautions:

Increased mortality in elderly patients with dementia: Elderly patients with dementia treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of thirteen placebo-controlled trials with various atypical antipsychotics in these patients showed a mean 1.6-fold increase in the death rate in the drug-treated patients. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular or infectious in nature.

Other relevant warnings and precautions:
- Body temperature disruption with antipsychotic use
- Orthostatic hypotension
- Angioedema
- Glucose abnormalities associated with atypical antipsychotics
- Hyperprolactinemia
- Weight gain
- Rare risk of priapism with antipsychotic use
- Antiketois effect
The most common side effects of LATUDA in adult patients with schizophrenia are:
- drowsiness/sleepiness
- feeling of restlessness (akathisia)
- abnormal movements, tremor, muscle stiffness, slowing of movement
- nausea

The most common side effects of LATUDA in adolescent patients (15-17 years) with schizophrenia are:
- drowsiness/sleepiness
- nausea
- feeling of restlessness (akathisia)
- abnormal movements, tremor, muscle stiffness, slowing of movement
- vomiting

The most common side effects of LATUDA in adult patients with depression associated with bipolar disorder are:
- feeling of restlessness (akathisia)
- abnormal movements, tremor, muscle stiffness, slowing of movement

The most common side effects of LATUDA in adolescent patients (13-17 years) with depression associated with bipolar disorder are:
- nausea
- weight gain
- inability to sleep (insomnia)
- drowsiness/sleepiness

LATUDA is available in five tablet strengths: 20 mg, 40 mg, 60 mg, 80 mg and 120 mg.

For more information:
Please consult the Product Monograph at http://www.sunovion.ca/monographs/latuda.pdf for important information relating to adverse reactions, interactions and dosing information which have not been discussed in this piece.

The Product Monograph is also available by calling 1-866-260-6291.

Sunovion Pharmaceuticals Canada Inc. contact information:
Medical Information or to Report an Adverse Drug Reaction
1-866-933-6799 Fax
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About Sumitomo Dainippon Pharma Co., Ltd.
Sumitomo Dainippon Pharma is one of 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.

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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 Inc. is a wholly-owned direct subsidiary of Sumitomo Dainippon Pharma Co., Ltd. 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.

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References

Language: English
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References

Language: English
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