Results demonstrate a benefit to increasing LATUDA dose in patients who initially do not respond to treatment

The study found that LATUDA 20 mg/day was not associated with significant improvement in psychotic symptoms in adult patients with schizophrenia, indicating that the lowest effective dose of LATUDA for the treatment of schizophrenia is 40 mg/day, consistent with current prescribing information. In addition, the study found that in adults with schizophrenia who did not respond to two weeks of treatment with LATUDA 80 mg/day, increasing the dose to 160 mg/day resulted in significant symptom improvement over the next four weeks when compared to those who continued taking LATUDA 80 mg/day.

In the treatment of patients with schizophrenia, an important clinical concern is how to address early non-response to therapy,” said John Kane, M.D., Chairman, Department of Psychiatry, The Zucker Hillside Hospital, Glen Oaks, New York, and one of the study authors. “These study data provide clinically important evidence to inform decisions about when to increase medication dosage.”

This randomized, double-blind, placebo-controlled study investigated the efficacy of low-dose LATUDA (20 mg/day) in adult patients with schizophrenia who demonstrated inadequate initial response to standard dose Latuda® (lurasidone HCl).

LATUDA was generally well-tolerated. Serious treatment-emergent adverse events (TEAEs) were reported in three patients in the LATUDA 20 mg/day group, four patients in the early non-respondent LATUDA 80 mg/day group, one patient in the early non-responder LATUDA 160 mg/day group and eight patients in the placebo group. In early non-responders, patients whose dose was increased to LATUDA 160 mg/day reported a greater incidence of anxiety, abdominal discomfort, akathisia, insomnia, and somnolence compared with patients who continued on LATUDA 80 mg/day. LATUDA demonstrated low rates of change in weight and metabolic parameters.

“Few randomized, placebo-controlled studies have evaluated dose escalation as a strategy for addressing early nonresponse to antipsychotic therapy,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer, Sunovion. “Sunovion is pleased to contribute to the important medical discourse on how to manage patients with schizophrenia who do not respond to initial treatment.”

These data were presented at multiple U.S. and international scientific meetings in 2015.

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. 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.

About LATUDA

LATUDA is FDA-approved to treat adult patients with:

- Major depressive episodes associated with bipolar I disorder (bipolar depression) when used alone or with lithium or valproate
- Schizophrenia

The efficacy of LATUDA was established in a 6-week monotherapy study and a 6-week add-on therapy study with lithium or valproate in adult patients with bipolar depression. The efficacy of LATUDA in the treatment of adults with schizophrenia was established in five 6-week controlled studies. The effectiveness of LATUDA for longer-term use, that is, for more than 6 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.

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; and nausea.

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

LATUDA is not approved for the treatment of patients under the age of 18 years.

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.

Neuropsychiatric 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 healthcare 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 or 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 healthcare provider should check your blood sugar before you start LATUDA and during therapy. Call your healthcare provider if you have any of these symptoms of high blood sugar (hyperglycemia) while taking LATUDA: feel very thirsty, urine 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 healthcare 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 healthcare provider if you experience a lack of menstrual periods, leaking or enlarged breasts, or impotence.