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Sunovion announces results from Phase 3 clinical study of new drug in children, adolescents with bipolar depression

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Sunovion Pharmaceuticals Inc. (Sunovion) today announced post-hoc analysis results of a positive Phase 3 placebo-controlled clinical study, as well as interim data from a long-term open-label extension study evaluating Latuda® (lurasidone HCI) in children and adolescents (10 to 17 years of age) with major depressive episodes associated with bipolar I disorder (bipolar depression).

The results showed that six weeks of treatment with LATUDA was associated with statistically significant and clinically meaningful improvement in a wide range of depressive symptoms compared to placebo and that long-term treatment with LATUDA for 28 weeks was well-tolerated and continued to improve depressive symptoms with minimal effect on weight and metabolic parameters in children and adolescents with bipolar depression. Results were presented at a scientific meeting in Washington, D.C., being held October 23-28, 2017.

LATUDA is an atypical antipsychotic agent approved in the United States for the treatment of bipolar depression as monotherapy and as adjunctive therapy with lithium or valproate in adults and for the treatment of schizophrenia in adults and adolescents (13 to 17 years of age).

"Depressive symptoms can be severely debilitating to schoolwork and social activities in children and adolescents living with bipolar disorder, which is recognized as the fourth leading cause of disability among children and adolescents around the world," said Kiki Chang, M.D., clinical study investigator. "The findings presented today are encouraging, as we need additional treatment options that are well tolerated and can be used on an ongoing basis by children and adolescents who live with bipolar depression."

"Sunovion is committed to advancing the understanding of serious psychiatric conditions," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for

Sumitomo Dainippon Pharma Group. "Given the significant impact bipolar depression can have on children and adolescents, it is encouraging to see results that support the potential for LATUDA to be an effective and well-tolerated treatment for this population."

Sunovion submitted a supplemental New Drug Application (sNDA) for the use of LATUDA in children and adolescents (10 to 17 years of age) with bipolar depression that was accepted for review by the U.S. Food and Drug Administration (FDA) on June 30, 2017.

Phase 3 Study Results

Full Phase 3 study results were recently published in the *Journal of the American Academy of Child and Adolescent Psychiatry.*[1] 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 mg/day), 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 (-21.0 vs. -15.3; effect size = 0.45, $p<0.0001$).

A post-hoc item analysis of the CDRS-R endpoint presented today showed that LATUDA effectively treated a wide range of depressive symptoms. Compared to placebo, patients randomized to LATUDA demonstrated significantly greater improvement on 13 of the 17 CDRS-R items including social withdrawal, sleep disturbance, listless speech, depressed facial affect, excessive guilt, difficulty having fun, depressed feelings, low self-esteem, excessive weeping, hypoactivity, impaired schoolwork, irritability and appetite disturbance. Changes were not significant between the LATUDA group and placebo group in four CDRS-R items, including excessive fatigue, physical complaints, morbid ideation and suicidal ideation.

LATUDA was generally well-tolerated with minimal effects on weight, metabolic parameters and prolactin levels. Most common adverse events (AEs) with an incidence greater than five percent of LATUDA-treated patients and greater than placebo, included nausea, somnolence, weight increase, vomiting, dizziness and insomnia.

Long-term Open Label Extension Study Interim Analysis Results

A total of 223 participants who completed the six-week trial enrolled in a two-year, open-label, flexible dose, extension study (NCT01914393). Results from an interim analysis showed that among the 155 people who completed 28 weeks of treatment, LATUDA was generally well-tolerated with similar adverse events to those reported during the six-week pivotal study. The most common AEs with an incidence greater than 10 percent were headache (19.7 percent), somnolence (18.5 percent) and nausea (14.3 percent).

Minimal effects were observed on weight, metabolic parameters and prolactin levels. The mean change in weight from double-blind baseline to Week 28 of the open-label extension study was +3.0 kg (as compared to an expected weight gain of +2.3 kg based on normative CDC data). The median change in prolactin from baseline to Week 28 was +2.0 ng/mL for females and +1.6 ng/mL for males. Median change in metabolic parameters from baseline to Week 28 was -4.5 mg/dL in total cholesterol, -3.0 mg/dL in LDL cholesterol, -2.0 mg/dL in triglycerides and +1.0 mg/dL in glucose. No participants in the study had a QTcF≥460 or an increase in QTcF of ≥ 60 milliseconds.

At 28 weeks, participants who were treated with LATUDA throughout the initial six-week trial had continued improvement in the CDRS-R total score in the open-label long-term extension phase (-7.3). Continued improvement in the open-label phase was similarly observed on the Clinical Global Impression-Bipolar Version, Severity of Illness (CGI-BP-S) depression score (-1.0).

Source:

http://news.sunovion.com/press-release/sunovion-presents-data-phase-3-studies-latuda-lurasidone-hcl-children-and-adolescents