MetSy elevates the risk of developing type II diabetes, cardiovascular disease, and premature morbidity. Lumateperone (LUMA), a mechanistically novel antipsychotic that simultaneously modulates serotonin, dopamine, and glutamate neurotransmission, is FDA-approved for the treatment of schizophrenia and depressive episodes associated with bipolar I or bipolar II disorder. This distinct pharmacological profile has been associated with favorable tolerability and a low risk of adverse metabolic effects in clinical trials.

LUMA 42-mg monotherapy was evaluated in 2 randomized, double-blind, placebo (PBO)-controlled studies (Study 401 [NCT02600494]; Study 404 [NCT03249376]) in patients with a major depressive episode (MDE) associated with bipolar I or bipolar II disorder. This post hoc pooled analysis of these studies compares rates of MetSy with LUMA 42 mg and PBO in the treatment of bipolar depression.

Methods. The incidence and shift in MetSy were analyzed in data pooled from 2 studies that recruited patients aged 18–75 years with a confirmed diagnosis of bipolar I or bipolar II disorder who were experiencing an MDE (Montgomery-Åsberg Depression Rating Scale [MADRS] Total score ≥20 and Clinical Global Impression Scale-Bipolar Version-Severity [CGI-BP-S] score ≥4). Patients in these studies were randomized 1:1 to LUMA or PBO and treated for 6 weeks.

Results. The safety population comprised 746 patients (LUMA, 372; PBO, 374). Rates of MetSy were similar between groups at baseline (LUMA, 20.7%; PBO, 22.2%) and at the end of treatment (EOT, LUMA, 21.8%; PBO, 23.8%). More LUMA patients (36.4%) compared with PBO patients (30.1%) improved from having MetSy at baseline to no longer meeting MetSy criteria at EOT. The individual criteria that shifted the most from meeting MetSy criteria at baseline to no longer meeting criteria at EOT was BP for LUMA (46.8%) and glucose for PBO (43.2%). The rate of MetSy developed during treatment was similar for LUMA (10.8%) and PBO (10.7%) with approximately half of these patients (LUMA, 43.8%; PBO, 45.2%) shifting due to a change in ≥2 criteria.

Conclusion. In this post hoc analysis of 2 randomized, PBO-controlled trials in patients with a MDE associated with bipolar I or bipolar II disorder, LUMA 42 mg had similar rates of MetSy compared with PBO. These results suggest that LUMA 42 mg is a promising new treatment for bipolar depression with a favorable metabolic profile.

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Efficacy and Safety of Lurasidone in a Younger Population With Bipolar Depression: Pooled Post-hoc Analysis of Two Placebo-controlled Studies

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Abstract

Introduction. Early onset of bipolar disorder is associated with high rates of psychiatric comorbidity (e.g., anxiety disorders, ADHD, PTSD), high rates of recurrence, and marked impairment in functioning and quality of life. The aim of this analysis was to evaluate the efficacy and safety of lurasidone in bipolar depression in youth and young adult patients (10–30 years old).

Methods. Data from two 6-week, double-blind, placebo-controlled studies of lurasidone monotherapy for bipolar I depression were pooled for this analysis. In the 1st study, patients 10–17 years old were evaluated using the Children's Depression Rating Scale–Revised (CDRS-R) and the Clinical Global Impression-Bipolar Severity (CGI-BP-S) depression scale; in the 2nd study, a subgroup of adult patients (18–30 years old) were evaluated by CGI-BP-A, and the MADRS, with the latter being converted to a CDRS-R scores using a validated conversion algorithm.

Results. The safety population consisted of 465 patients (mean age, 17.1 years; mean age of onset, 14.1; mean CDRS-R total score, 60.8). 400 patients (85.7%) completed the study. For lurasidone vs. placebo, LS mean Week 6 change was -21.4 vs. -15.3 for the CDRS-R total score (P<0.0001; ES, 0.46); and -1.6 vs. -1.1 for the CGI-BP-S score (P<0.0001; ES, 0.50). Adverse events (≥5%) on lurasidone vs. placebo were nausea (15.9% vs. 5.2%), headache (15.1% vs. 13.1%), somnolence (7.9% vs. 3.8%), vomiting (5.2% vs. 3.3%), and weight increase (5.2% vs. 2.3%). No clinically meaningful changes were observed in weight, metabolic parameters, or prolactin.

Conclusions. In this post-hoc analysis of two placebo-controlled trials, lurasidone demonstrated clinically meaningful improvement of depressive symptoms in youth and young adults with bipolar depression. Lurasidone was generally safe, well-tolerated, and associated with minimal effects on weight, metabolic parameters, and prolactin.

Funding. Servier Laboratories (Aust.) Pty. Ltd., and Sunovion Pharmaceuticals Inc.

Long-Term Safety and Effectiveness of Lurasidone in Adolescents and Young Adults With Schizophrenia: Pooled Post-hoc Analyses of Two 12-month Extension Studies

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Abstract

Introduction. Earlier onset of schizophrenia, which occurs more commonly in males, is characterized by greater illness severity, chronicity, and functional impairment with a less favorable prognosis than later-onset schizophrenia. The aim of this pooled analysis was to evaluate the long-term safety and effectiveness of lurasidone in the treatment of schizophrenia in adolescents (13–17 years) and young adults (18–25 years).

Methods. The 2 pooled studies used similar designs and outcome measures. Patients (13–25 years) with schizophrenia completed an initial double-blind 6-week trial of lurasidone (40 and 80 mg/d), and (80 and 160 mg/d) in the young adult trial. In the open-label long-term trials, adolescent patients were treated with 20-80 mg/d of lurasidone, and adults were treated with 40–160 mg/d of lurasidone. Efficacy was evaluated based on the Positive and Negative Syndrome Scale (PANSS) and Clinical Global Impression-Severity Scale (CGI-S).

Results. The safety population consisted of 306 patients (mean age, 16.2 years; 208 patients (68.0%) who completed 12 months of treatment; 8.2% discontinued by 12 months due to an adverse event. Mean (SD) change in the PANSS total score from extension Baseline to Months 6 and 12 was -11.8 (13.9) and -15.3 (15.0), respectively (OC); and mean (SD) change in the CGI-S score was -0.8 (1.0) and -1.0 (1.1), respectively (OC). The most frequent adverse events were headache (17.6%), anxiety (11.4%), schizophrenia (9.8%), and nausea (9.8). No clinically meaningful changes were observed in weight, metabolic parameters, or prolactin.

Conclusions. In adolescents and young adults with schizophrenia, treatment with lurasidone was generally well-tolerated and effective. Long-term treatment was associated with continued reduction in symptoms of schizophrenia. Long-term treatment was associated with minimal effects on weight, metabolic parameters, and prolactin.

Funding. Angelini Pharma S.p.A. and Sunovion Pharmaceuticals Inc.

IVIG for Treatment-Resistant Psychosis For a Child with Turner Syndrome

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Abstract

Psychosis is defined as the presence of false beliefs or false perceptions. In children some causes of psychosis include psychiatric diagnosis such as schizophrenia and autism. However, it may also be secondary to medical conditions like various forms of encephalitis. Studies have shown that IVIG has been efficacious in the treatment of psychosis in the setting of autoimmune encephalitis.

A 9-year-old girl with a past medical history of Turner Syndrome, developmental delay, epilepsy, growth hormone deficiency, metabolic bone disease, and autism (ASD) presented with auditory and visual hallucinations that began June 2020. She began with her hearing voices that repeated the word "dead" and told her that she would not live. The hallucination later took the form of a man that would mock her, laugh about her parents dying, and tell her to kill them. The patient had associated symptoms of insomnia, anxiety, sadness, and increased anger. On her initial admission, CSF studies including culture and gram strain were unremarkable. NMDA, VHKC, and GAD65 antibodies were negative. At this time the hallucinations were thought to be due to ASD and she was prescribed Risperdal 0.25mg twice a day. Unfortunately, this did not improve her symptoms and from the time period of June 2020 to May 2021 she subsequently underwent trials of Risperdal, Zyprexa, Invega, Abilify, Thorazine, Haldol, and Clozaril. However, the symptoms persisted. Zoloft was prescribed, which was efficacious for anger and dysphoria. Trazodone, melatonin, and Remeron were tried for the treatment of insomnia, but did not cause enough improvement to continue the medications. Due to progression of command hallucinations with "the man" instructing her to hurt others, the patient was admitted July 2021 for administration of IVIG. Repeat CSF studies and brain MRI were unremarkable. From July 29, 2021 to August 1, 2021 she received three doses of IVIG which resulted in improvement of psychosis. Prior to administration, she was seeing "the man" throughout the day every single day, was sleeping only 3–4 hours a night, and having nightmares everyday. On evaluation 2 weeks after IVIG, she was only seeing "the man" 1–2 time a day, sleeping 6–8 hours a night, having nightmares 1–2 times a week, and her mood had improved.

This case illustrates the potential use of IVIG for the treatment of treatment-resistant psychosis. Although the cause of this patient's symptoms remains unclear, there were clear benefits from the administration of IVIG that were not seen with trials of antipsychotics.

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Real-World Treatment Patterns and Healthcare Resource Utilization in Patients Prescribed Benztropine: A Claims Analysis From 2017-2020

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Abstract

Introduction. We sought to examine real-world treatment patterns and healthcare resource utilization (HCRU) for patients receiving an antipsychotic (AP) and subsequently prescribed benztropine.

Methods. A retrospective analysis was conducted among patients with evidence of benztropine initiation using claims data from

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