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

Chris Davey, MPsy, PhD, FRANZCP1, Aswin Ratheesh, MBBS, MD, FRANZCP, PhD1,2, Michael Tocco, PhD2, Yongcai Mao, PhD2, David George3, Andrei Pikalov, MD, PhD3 and Manpreet K Singh, MD2

1Department of Psychiatry, The University of Melbourne, Parkville, Australia, 2Orygen, Centre for Youth Mental Health, Parkville, Australia, 3Sunovion Pharmaceuticals Inc, Teaneck, NJ, and Marlborough, MA, USA, 4Servier Laboratories (Aust.) Pty Ltd., Burnley, Australia and 5Psychiatry and Behavioral Sciences, Stanford University, Stanford, CA, USA

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 first 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 second 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.

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

Fabrizio Calisti, PhD1, Michael Tocco, PhD2, Yongcai Mao, PhD2, Andrei Pikalov, MD, PhD2 and Robert Goldman, PhD2

1Angelini RR&D (Regulatory, Research, & Development) - Angelini Pharma S.p.A., Viale Amelia, 70 - 00181 Rome, Italy and 2Sunovion Pharmaceuticals Inc, Teaneck, NJ, and Marlborough, MA, USA