Article: 1134
Topic: EPV03 - e-Poster 03: Bipolar Disorders

Long-term Treatment with Lurasidone in Older Adults with Bipolar Depression: Results of a 6 Month Open-label Study

B. Forester[1], M. Sajatovic[2], J. Tsai[3], H. Kroger[4], A. Pikalov[5], J. Cucchiaro[5], A. Loebel[5]

[1]Department of Psychiatry, Harvard Medical School, Boston, USA ; [2]Department of Psychiatry, Case Western Reserve University School of Medicine, Cleveland, USA ; [3]Medical Affairs, Sunovion Pharmaceuticals Inc, Marlborough, USA ; [4]Biostatistics, Sunovion Pharmaceuticals Inc, Fort Lee, USA ; [5]Clinical Development and Medical Affairs, Sunovion Pharmaceuticals Inc, Fort Lee, USA

Introduction: Long-term treatment of bipolar depression in the elderly has not been well-studied.
Objectives/Aims: To evaluate the long-term safety and tolerability of lurasidone in older adults (age ≥55 years) with bipolar I depression (BPD).
Methods: The older adult sample was analyzed from an extension study in which patients who completed one of three 6 week, double-blind, placebo-controlled trials received 6 months of open-label treatment with flexible doses of lurasidone 18.5-111 mg/d, either as monotherapy, or adjunctive to lithium or valproate.
Results: The older adult sample consisted of 55 patients (17.4% of total) on lurasidone monotherapy and 86 patients (17.3%) on adjunctive lurasidone. At the end of 6 months of treatment with lurasidone, monotherapy and adjunctive therapy, respectively, minimal changes were observed in mean weight (-1.0 kg; -0.4 kg); and median total cholesterol (-2.0 mg/dL; +6.0 md/dL), triglycerides (+2.5 mg/dL; +6.0 mg/dL), and HbA1c (0.0%; -0.1%). The 3 most common adverse events were fatigue (18.4%), insomnia (18.4%), headache (15.8%) in the monotherapy group, and akathisia (31.7%), insomnia (22.0%), tremor (19.5%) in the adjunctive group. Discontinuation due to adverse events was low in both groups (monotherapy, 7.3%; adjunctive, 9.3%). Improvement in depression was maintained during 6 months of treatment, with a mean change in MADRS scores of -15.7 for the monotherapy group, and -17.8 for the adjunctive therapy group (from acute study baseline).
Conclusions: Results of these secondary analyses suggest that lurasidone, in doses of 18.5-111 mg/day, was a safe and well-tolerated long-term treatment for bipolar depression in older adults.

NCT00868959.
Sponsored by Sunovion Pharmaceuticals Inc.

https://doi.org/10.1016/S0924-9338(15)30897-X Published online by Cambridge University Press