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Efficacy and Tolerability of Lurasidone in Older Adults with Bipolar Depression: Analysis of Two 6-week Double-blind, Placebo-controlled Studies

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

[1]Department of Psychiatry, Case Western Reserve University School of Medicine, Cleveland, USA ; [2]Department of Psychiatry, Harvard Medical School Boston MA, Boston, 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: The acute treatment of bipolar depression in the elderly has not been well-studied.
Objectives/Aims: To evaluate the acute efficacy and tolerability of lurasidone in older adults (age ≥55 years) with bipolar I depression (BPD).
Methods: The older adult sample was analyzed from two, randomized, double-blind, 6-week studies of BPD patients with a Montgomery-Asberg Depression Rating Scale (MADRS) score ≥20: a monotherapy trial (lurasidone 18.5-56 mg/d vs 74-111 mg/d vs placebo); and an adjunctive trial (with lithium or valproate; lurasidone 18.5-111 mg/d vs placebo).
Results: The older adult sample consisted of 83 patients (17.1%) on monotherapy, and 53 patients (15.6%) on adjunctive therapy. At Week 6, mean change in MADRS was significantly greater for lurasidone 18.5-56 mg (-15.4; $P<0.01$; effect size=0.86) and 74-111 mg (-14.1; $P<0.02$; effect size=0.74) vs placebo (-7.1). Adjunctive therapy with lurasidone (vs placebo) was associated with numerically greater improvement at Week 6 in MADRS (-13.9 vs. -11.1; ns; effect size=0.26). Among older adults in the monotherapy study, discontinuation due to adverse events occurred in 7.7% of patients on lurasidone 18.5-56 mg, 6.7% on lurasidone 74-111 mg, and 3.7% on placebo; and in the adjunctive therapy study, discontinuation due to adverse events occurred in 3.8% of patients on lurasidone, and 7.4% on placebo.
Conclusions: Results of these analyses suggest that lurasidone, in doses of 18.5-111 mg, was an efficacious and well-tolerated acute treatment for bipolar depression in older adults. Significance vs placebo was achieved with lurasidone monotherapy, however, adjunctive therapy with lurasidone did not reach statistical significance.
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