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A 6-MONTH, RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE BLIND TRIAL OF ZIPRASIDONE PLUS A MOOD STABILIZER IN SUBJECTS WITH BIPOLAR I DISORDER

E. Vieta[1], C. Bowden[2], K. Ice[3], O. Gurtovaya[3], J. Schwartz[3], P. Wang[3]

[1]Clinical Institute of Neuroscience Hospital Clinic, University of Barcelona, IDIBAPS, CIBERSAM, Barcelona, Spain, [2]Department of Psychiatry, University of Texas Health Sciences Center, San Antonio, [3]Pfizer Global Research and Development, New London, USA

Background: The objective of this study was to evaluate the efficacy and safety of ziprasidone adjunctive to a mood stabilizer for the maintenance treatment of bipolar mania.

Methods: Male and female subjects with bipolar I disorder with MRS ³ 14 were enrolled. Subjects achieving ≥ 8 consecutive weeks of stability with open-label ziprasidone (80-160 mg/d) and lithium or divalproex were randomized into the 6-month double-blind maintenance period, to ziprasidone + mood stabilizer or placebo + mood stabilizer. The primary and key secondary end points were the time to intervention for a mood episode, and time to discontinuation for any reason, respectively. Inferential analysis was performed using a Kaplan-Meier product-limit estimator (Log-rank test).

Results: 127 and 112 subjects were randomized to and treated in the ziprasidone and placebo groups, respectively. The time to intervention for a mood episode was significantly different, favoring ziprasidone (p = 0.0104). 19.7% and 32.4% of ziprasidone and placebo subjects, respectively, required intervention for a mood episode. Time to discontinuation for any reason was significantly different (p = 0.0047), favoring ziprasidone. Among treatment-emergent adverse events occurring in the double-blind period, the only event occurring more frequently in the ziprasidone group than in the placebo group (≥ 5%) was tremor (6.3% vs 3.6%, respectively).

Conclusions: These results demonstrate that ziprasidone is an effective, safe, and well-tolerated adjunctive treatment with a mood stabilizer for long-term maintenance treatment of bipolar mania.

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