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EFFECTIVENESS OF EXTENDED-RELEASE FORMULATION OF QUETIAPINE AS MONOTHERAPY FOR THE TREATMENT OF ACUTE BIPOLAR MANIA (TRIAL D144CC00004)

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Objectives: To evaluate the effectiveness of extended release quetiapine fumarate (quetiapine XR) as once-daily monotherapy for manic symptoms in bipolar I disorder.

Methods: In this 3-week, randomized, parallel-group, double-blind study, adults with bipolar I disorder (most recent episode manic or mixed; with or without rapid cycling) were randomized to once-daily treatment with either quetiapine XR (n=149; Day 1, 300 mg; Day 2, 600 mg; Day 3 through Week 3, 400-800 mg flexibly dosed) or placebo (n=159). Primary outcome measure was change from baseline to Week 3 in Young Mania Rating Scale (YMRS) total score. Secondary outcome measures included YMRS response and remission and change in Clinical Global Impression-Bipolar (CGI-BP)-Severity of Illness and -Change scales. Change from baseline was compared between groups with analysis of covariance, using the last observation carried forward approach for missing data.

Results: Once-daily quetiapine XR was associated with significant, sustained improvement in manic symptoms compared with placebo, beginning on Day 4 ($P< 0.001$) and continuing through Week 3 (mean change: -14.34 versus -10.52; $P< 0.001$). At Week 3, quetiapine XR-treated patients showed significantly greater response ($P< 0.01$) and remission ($P< 0.01$) rates and improvement in CGI-BP-associated scores than placebo-treated patients. Adverse events were mild to moderate in intensity, the most common being sedation, dry mouth, and somnolence for quetiapine XR.

Conclusions: Once-daily quetiapine XR monotherapy (400-800 mg) was efficacious (from Day 4 through Week 3) and generally well tolerated in the treatment of manic episodes associated with bipolar I disorder.
Supported by funding from AstraZeneca Pharmaceuticals LP.

https://doi.org/10.1016/S0924-9338(09)70806-5 Published online by Cambridge University Press