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EFFECTIVENESS OF THE NEW EXTENDED-RELEASE FORMULATION OF QUETIAPINE AS MONOTHERAPY FOR THE TREATMENT OF ACUTE BIPOLAR DEPRESSION (TRIAL D144CC00002)

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Objectives: To evaluate the effectiveness of extended-release quetiapine fumarate (quetiapine XR) as once-daily monotherapy for bipolar depression.
Method: Patients in this double-blind, placebo-controlled study were acutely depressed adults with bipolar I or II disorder (with or without rapid cycling), and were randomized to 8 weeks of once-daily treatment with quetiapine XR 300 mg (n=133) or placebo (n=137). The primary outcome measure was change from baseline to endpoint (Week 8) in Montgomery-Åsberg Depression Rating Scale (MADRS) total score. Secondary outcome measures included response (MADRS total score reduction ≥50%) and remission (MADRS total score ≤12) rates at endpoint, changes from baseline to endpoint in MADRS item scores, and Clinical Global Impressions-Bipolar (CGI-BP) severity of illness and change. Change from baseline was compared between groups with analysis of covariance using last observation carried forward approach.

Results: Quetiapine XR 300 mg/d was significantly more effective than placebo in improving depressive symptoms, from first assessment (Week 1; $P < 0.001$) to endpoint ($P < 0.001$). Compared with placebo, quetiapine XR was associated with higher response ($P < 0.001$) and remission ($P < 0.05$) rates and greater improvements from baseline to endpoint in MADRS total score (-17.43 vs -11.92; $P < 0.001$), MADRS item scores for core symptoms of depression, and CGI-BP-related outcomes at Week 8. Most common adverse events with quetiapine XR were dry mouth, somnolence, and sedation.

Conclusions: Quetiapine XR (300 mg) once-daily monotherapy was efficacious (from Weeks 1 through 8) compared with placebo and generally well tolerated in bipolar depression.
Supported by funding from AstraZeneca Pharmaceuticals LP.

https://doi.org/10.1016/S0924-9338(09)70807-7 Published online by Cambridge University Press