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QUETIAPINE OR LITHIUM VERSUS PLACEBO FOR MAINTENANCE TREATMENT OF BIPOLAR I DISORDER AFTER STABILIZATION ON QUETIAPINE

W.A. Nolen[1], R.H. Weisler[2], A. Neijber[3], Å. Hellqvist[4], B. Paulsson[3]

[1]University Medical Center Groningen, University of Groningen, Groningen, The Netherlands, [2]Duke University Medical Center, University of North Carolina at Chapel Hill, Raleigh, USA, [3]AstraZeneca R&D, Södertälje, [4]AstraZeneca R&D, Mölndal, Sweden

Purpose: Quetiapine combined with lithium or divalproex is an effective maintenance treatment for bipolar I disorder.[1,2] This double-blind, randomized trial (D1447C00144) investigated quetiapine monotherapy as maintenance treatment.

Methods: Adults experiencing manic, depressed, or mixed episodes of bipolar disorder received open-label quetiapine. Patients achieving stabilization (YMRS ≤12 and MADRS ≤12, 4 consecutive weeks) were randomized to continue quetiapine (300-800 mg/d) or to switch to placebo or lithium (target serum 0.6-1.2 mEq/L) for up to 104 weeks or recurrent mood event. The primary endpoint was time to recurrence of any mood event. The study was terminated when interim analysis provided positive results.

Results: Of 2438 patients starting open-label quetiapine, 1226 (50.3%) were randomized to study medication with 1172 in the ITT population. Mean median quetiapine dose was 546 mg/d; mean median lithium serum level was 0.63 mEq/L. Time to recurrence of any mood event was longer for continued quetiapine versus switching to placebo (HR, 0.29; 95% CI, 0.23-0.38; P< 0.0001), for switching to lithium versus switching to placebo (HR, 0.46; 95% CI, 0.36-0.59; P< 0.0001), and for continued quetiapine versus switching to lithium (HR, 0.66; 95% CI, 0.49-0.88; P=0.005). Safety findings were consistent with known profiles.

Conclusions: In patients stabilized on quetiapine, continued quetiapine significantly decreased time to recurrence of any mood event versus switching to placebo. Switching to lithium was also more effective than switching to placebo and conferred no additional benefit versus continuing quetiapine.Supported by funding from AstraZeneca Pharmaceuticals LP.

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