

PW01-37 - LONG-TERM EFFICACY OF QUETIAPINE IN COMBINATION WITH LITHIUM OR DIVALPROEX ON MIXED SYMPTOMS IN BIPOLAR I DISORDER

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Objective: To determine the efficacy of QTP in patients with bipolar I disorder with mixed symptoms.

Method: Data from 2 phase III studies (D1447C00126 and D1447C00127) were pooled. Unlike previous analyses of these studies, mixed events were analyzed separately. Patients received QTP (400-800 mg/d)+Li/DVP to achieve ≥ 12 weeks of clinical stability followed by double-blind treatment with QTP (400-800 mg/d)+Li/DVP or PBO+Li/DVP for up to 104 weeks. Primary endpoint was time to first mood event post-randomization.

Results: 1326 patients were included in the ITT population. Relative to PBO, QTP significantly increased time to recurrence of mixed events ($P < 0.0001$). 445 ITT patients had a most recent mixed episode at study entry. In these patients, mood events were reported by fewer patients on QTP+Li/DVP (21.0%) than on PBO+Li/DVP (53.9%). These events included mixed (6.4% vs 22.1%), pure manic (5.0% vs 13.3%), and pure depressed events (9.6% vs 18.6%). Time to recurrence of mood events was significantly longer for patients on QTP+Li/DVP than for those on PBO+Li/DVP for mixed (HR, 0.23, 95% CI, 0.13-0.42, $P < 0.0001$), pure manic (HR, 0.30, 95% CI, 0.15-0.60, $P = 0.0007$), and pure depressed events (HR, 0.38, 95% CI, 0.22-0.64, $P = 0.0003$). No new safety concerns were noted.

Conclusions: In stable patients with bipolar I disorder, QTP+Li/DVP significantly increased: a) time to recurrence of mood events compared with PBO in patients with mixed symptoms at study entry; and b) time to occurrence of mixed mood events in patients with any mood episode at study entry.

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