

PW01-38 - MAINTENANCE TREATMENT WITH QUETIAPINE ADDED TO EITHER LITHIUM OR DIVALPROEX IN BIPOLAR I DISORDER

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Objective: Combined data are presented from 2 long-term studies (D1447C00126; D1447C00127) of QTP in combination with Li or DVP in the prevention of mood events in bipolar I disorder. Data from Li and DVP treatment groups are analyzed separately to determine the added benefit of QTP.

Methods: 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. Li or DVP treatment was openly assigned at the discretion of the investigator. Primary endpoint was time to first mood event post-randomization.

Results: 1326 patients were included in the ITT population. In both Li and DVP groups, the risk of recurrence of any mood event was significantly reduced following treatment with QTP relative to placebo (HR, 0.32, 95% CI, 0.24-0.44 and HR, 0.28, 95% CI, 0.21-0.37; for Li and DVP, respectively; $P < 0.0001$ for both). This trend was repeated for risk of recurrence of mania and depression events ($P < 0.0001$ vs placebo). Comparison of QTP+Li versus QTP+DVP groups revealed no differences in the risk of recurrence of mood, mania, or depression events. Safety data were generally consistent with the recognized safety profiles of QTP, Li, and DVP.

Conclusions: In stable patients with bipolar I disorder, treatment with QTP, in combination with either Li or DVP, resulted in similar significant increases in the time to recurrence of a mood event (mania or depression) compared with placebo, regardless of Li or DVP co-treatment.

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