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EFFECTS OF ONCE-DAILY ADJUNCT QUETIAPINE XR ON SLEEP DISTURBANCE IN PATIENTS WITH MDD: A POOLED ANALYSIS FROM TWO ACUTE STUDIES

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Introduction: Disrupted sleep is common in depression.

Objectives: Investigate effects of adjunct extended release quetiapine fumarate (QTP-XR) on sleep disturbance and quality in patients with MDD and inadequate response to antidepressant (AD) therapy.

Methods: Data were pooled from two (D1448C00006/D1448C00007) 6-week, double-blind, randomised, placebo (placebo+AD)-controlled studies of adjunct QTP-XR (150mg/day and 300mg/day). Primary endpoint: MADRS total score change versus placebo+AD. Secondary endpoints (post hoc): change from randomisation in MADRS item 4 (reduced sleep), HAM-D items 4, 5 and 6 (early-, middle- and late-insomnia), sleep disturbance factor (HAM-D items 4+5+6) and sleep quality (PSQI global score). MADRS total score change in patients with baseline HAM-D sleep disturbance factor score ≥ 4 or < 4 (high and low sleep disturbance, respectively) was evaluated.

Results: 919 patients received adjunct QTP-XR: 150mg/day (n=309), 300mg/day (n=307), placebo+AD (n=303). At Week 6, adjunct QTP-XR (both doses) reduced MADRS item 4, HAM-D sleep disturbance factor, HAM-D items 4, 5 and 6 and PSQI global scores from baseline versus placebo+AD ($p < 0.001$). In patients with baseline HAM-D ≥ 4 (n=226, 215 and 210, respectively) adjunct QTP-XR (both doses) improved ($p < 0.01$) MADRS total score versus placebo+AD from Week 1 onward. In patients with baseline HAM-D < 4 (n=83, 92, 93, respectively) adjunct QTP-XR (both doses) improved (not statistically significantly) MADRS total score versus placebo+AD at Week 6.

Conclusions: Adjunct QTP-XR significantly restored sleep and improved sleep quality in patients with MDD and inadequate response to AD. Significant improvement in depressive symptoms was demonstrated with adjunct QTP-XR in patients with MDD and high baseline sleep disturbance. AstraZeneca funded.