

## P01-249

### POOLED ANALYSIS OF ADJUNCTIVE EXTENDED RELEASE QUETIAPINE FUMARATE (QUETIAPINE XR) IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER (MDD)

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**Aim:** To evaluate quetiapine XR as adjunct to ongoing antidepressant therapy in patients with MDD showing inadequate response to antidepressant treatment.

**Methods:** Data were analysed from two 6-week, multicentre, double-blind, randomised, placebo-controlled studies (D1448C00006; D1448C00007), prospectively designed to be pooled. Outpatients received adjunctive quetiapine XR 150mg/day (n=309), 300mg/day (n=307), placebo (n=303). Primary endpoint: change at Week 6 in MADRS total score. Other assessments included: MADRS individual item scores, HAM-A total scores, MADRS response and remission; AE reporting.

**Results:** Quetiapine XR 150mg/day and 300mg/day ( $p < 0.001$ ) reduced MADRS total scores versus placebo at Week 6 (-14.5, -14.8, -12.0) and Week 1 (-7.8, -7.3, -5.1). Subgroup analyses showed the therapeutic effect of quetiapine XR was neither limited to nor driven by factors such as gender or antidepressant class (SSRI/SNRI). Quetiapine XR demonstrated consistent improvements in individual MADRS items: 150mg/day and 300mg/day significantly improved 4/10 and 7/10 items at Week 6 versus placebo. At Week 6, MADRS response ( $\geq 50\%$  decrease in total score) was 53.7% ( $p=0.063$ ), 58.3% ( $p < 0.01$ ) versus 46.2%; MADRS remission (total score  $\leq 8$ ) was 35.6% ( $p < 0.01$ ), 36.5% ( $p < 0.001$ ) versus 24.1% for quetiapine XR 150mg/day and 300mg/day and placebo, respectively. Quetiapine XR 150mg/day and 300mg/day improved HAM-A total scores versus placebo at Week 1 (-4.8 [ $p < 0.001$ ], -4.2 [ $p < 0.01$ ], -3.0) and Week 6 (-8.9 [ $p < 0.01$ ], -9.1 [ $p < 0.001$ ], -7.3). AEs ( $\geq 10\%$ ) were dry mouth, somnolence, sedation, dizziness, fatigue, constipation and headache with quetiapine XR.

**Conclusion:** In patients with MDD and an inadequate response to antidepressant therapy adjunctive quetiapine XR is effective and generally well tolerated.