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ANALYSIS OF POOLED DATA: ONCE-DAILY EXTENDED RELEASE QUETIAPINE FUMARATE (QUETIAPINE XR) MONOTHERAPY IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER (MDD)

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Aim: To evaluate efficacy and tolerability of quetiapine XR monotherapy in patients with MDD.

Methods: Data were analysed from two 6-week, multicentre, double-blind, placebo-controlled studies (D1448C00001, D1448C00002), prospectively designed to be pooled. Outpatients received quetiapine XR 150mg/day (n=315), 300mg/day (n=323), placebo (n=330). Primary outcome: change at Week 6 in MADRS total scores. Other assessments: MADRS individual item scores, HAM-A total scores, MADRS response and remission; AE reporting.

Results: Quetiapine XR 150mg/day and 300mg/day reduced MADRS total scores at Week 6 (-14.7 and -14.7; $p< 0.001$) versus placebo (-11.1); significant reductions were also seen at Week 1 ($p< 0.001$).
Subgroup analyses showed the therapeutic effect of quetiapine XR was neither limited to nor driven by factors such as gender, age or depression severity.
Quetiapine XR demonstrated consistent improvements in MADRS items: both doses significantly improved 8/10 items at Week 6 versus placebo. At Week 6, MADRS response (≥50% decrease in total score) was 52.7% ($p< 0.001$), 49.5% ($p< 0.001$) versus 33.0%; MADRS remission (total score ≤10) was 33.7% ($p< 0.01$), 34.7% ($p< 0.01$) versus 24.2% 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 (-4.6 [$p< 0.01$], -4.7 [$p< 0.01$], -3.6) and Week 6 (-8.1 [$p< 0.001$], -7.9 [$p< 0.001$], -6.2). Common AEs (≥10%) were dry mouth, sedation, somnolence, dizziness, headache and nausea with quetiapine XR.

Conclusion: In patients with MDD, quetiapine XR monotherapy improved a broad range of depressive symptoms, with improvements seen from Week 1. Quetiapine XR was generally well tolerated.

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