

## PW01-25 - EXTENDED RELEASE QUETIAPINE FUMARATE (QUETIAPINE XR) IN PATIENTS WITH MDD: RESULTS FROM 8 PLACEBO-CONTROLLED STUDIES

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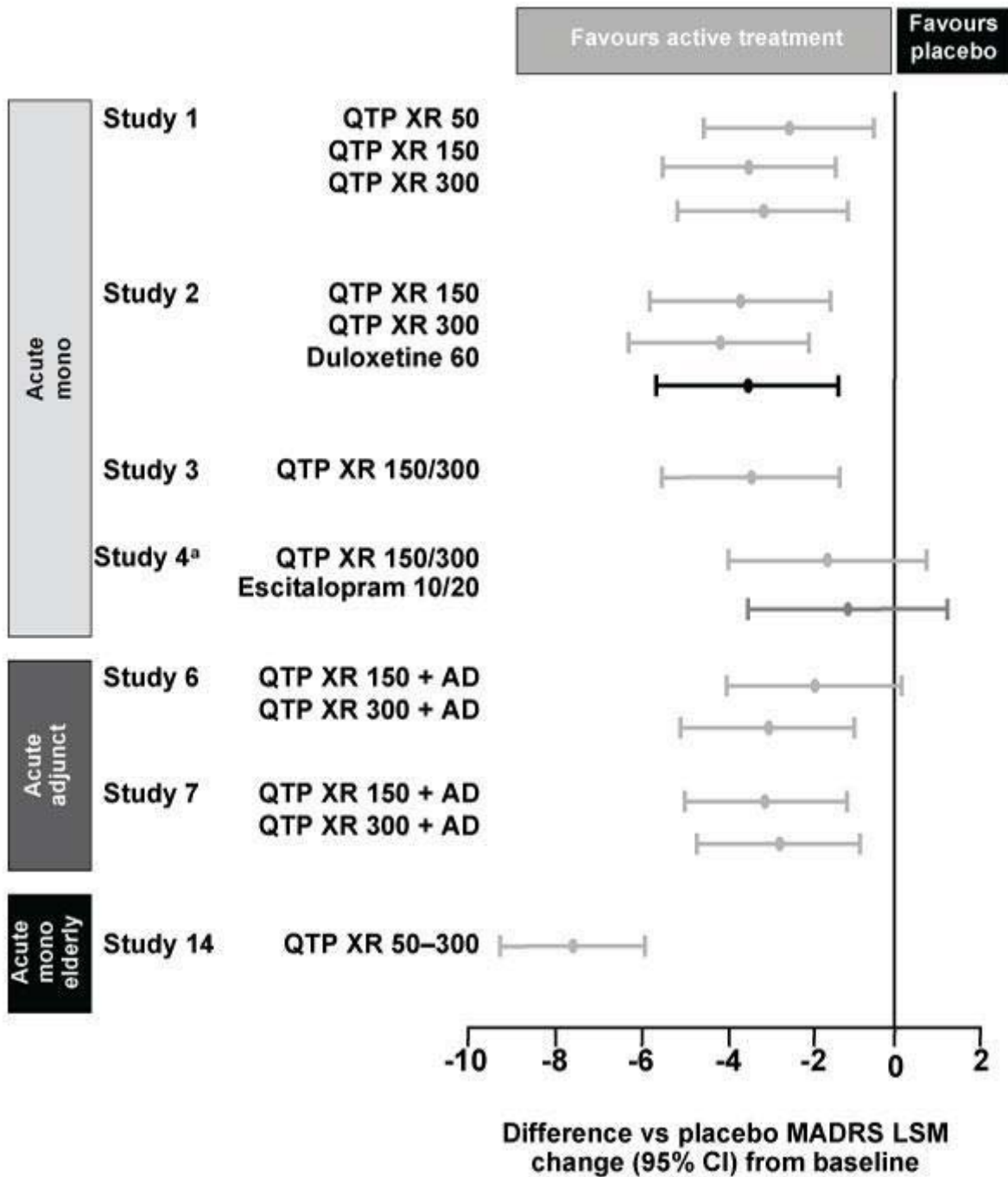
**Objectives:** To evaluate once-daily extended release quetiapine fumarate (quetiapine XR) as monotherapy (50, 150 and 300mg/day) (acute and maintenance treatment) or adjunct treatment (150 and 300mg/day) in patients with MDD.

**Methods:** Eight (7 acute, 1 maintenance) placebo-controlled studies were analysed. Primary endpoints: change from randomisation in Montgomery-Åsberg Depression Rating Scale (MADRS) scores (acute); time from randomisation to depressed event (maintenance). Statistical analyses: ANCOVA for difference between quetiapine XR and placebo in LSM change in MADRS total score from randomisation to study end (LOCF; acute); hazard ratio (HR) for time to recurrence of a depressed event (maintenance).

**Results:** Figure 1 shows treatment differences (95% CIs) for primary efficacy variable for the seven acute studies. Four monotherapy studies (D1448C00001, D1448C00002, D1448C00003, D1448C00014) were significant in favour of quetiapine XR; Study D1448C00004 (monotherapy) was not. Studies D1448C00006 and D1448C00007 were significant in favour of adjunct quetiapine XR. Time from randomisation to depressed event (Study D1448C00005) significantly increased with quetiapine XR; HR (95% CI): 0.34(0.25, 0.46);  $p < 0.001$ ; number of depressed events: 55, quetiapine XR; 132, placebo. Safety findings were consistent with the known tolerability profile of quetiapine.

**Conclusions:** Quetiapine XR consistently demonstrated antidepressant efficacy, with 6/7 acute studies positive in favour of quetiapine XR (monotherapy or adjunct). Quetiapine XR maintenance therapy significantly reduced risk of a depressed event, demonstrating relapse prevention. AstraZeneca funded

**Figure 1. Change from baseline in MADRS total score for quetiapine XR versus placebo**



<sup>a</sup>failed study, quetiapine XR and escitalopram failed to separate from placebo

[Figure 1]