

PW01-03 - EVALUATION OF THE EFFECTS OF QUETIAPINE XR MONOTHERAPY ON SLEEP DISTURBANCE IN PATIENTS WITH MDD

B. Bandelow¹, K. Demyttenaere², G. Papakostas^{3,4}, M. Trivedi⁵, J. Szamosi⁶, W. Earley⁷, H. Eriksson⁶

¹*Department of Psychiatry and Psychotherapy, University of Goettingen, Goettingen, Germany,*

²*University Hospital Gathuisburg, Leuven, Belgium,* ³*Psychiatry, Harvard Medical School,* ⁴*Department of Psychiatry, Massachusetts General Hospital, Boston, MA,* ⁵*Department of Psychiatry, UT Southwestern Medical Center-Dallas, Dallas, TX, USA,* ⁶*AstraZeneca R&D, Södertälje, Sweden,* ⁷*AstraZeneca Pharmaceuticals, Wilmington, DE, USA*

Objectives: Evaluate the effects of once-daily extended release quetiapine fumarate (quetiapine XR) monotherapy on sleep disturbance in patients with major depressive disorder (MDD).

Methods: Pooled data from four 6- or 8-week placebo-controlled quetiapine XR (50-300mg/day, administered in the evening) monotherapy studies (D1448C00001, D1448C00002, D1448C00003, D1448C00004) were analysed. Primary endpoint: change from randomisation in Montgomery-Åsberg Depression Rating Scale (MADRS) scores. Post-hoc analyses assessed changes in: MADRS item 4 (reduced sleep); Hamilton Rating Scale for Depression (HAM-D) items 4 (insomnia-early), 5 (insomnia-middle) and 6 (insomnia-late) and sleep disturbance factor (items 4+5+6); Pittsburgh Sleep Quality Index (PSQI) total and item scores. MADRS total score change was analysed for patients experiencing high (baseline HAM-D sleep disturbance factor score ≥ 4) and low (baseline HAM-D sleep disturbance factor score < 4) sleep disturbance.

Results: In total, 2,116 patients were randomised. At last assessment, quetiapine XR (all doses combined) significantly ($p < 0.001$) reduced MADRS item 4, HAM-D sleep disturbance factor and items 4, 5 and 6 and PSQI total scores from baseline versus placebo. Quetiapine XR significantly ($p < 0.001$) improved MADRS total score from baseline versus placebo at all time points in patients experiencing high sleep disturbance ($n=865$, quetiapine XR; $n=514$, placebo). Quetiapine XR improved MADRS total score versus placebo in patients with low sleep disturbance ($n=252$, quetiapine; $n=121$, placebo): difference significant at Weeks 2 ($p < 0.001$), 4 ($p < 0.05$) and 6 ($p < 0.05$).

Conclusions: Quetiapine XR monotherapy improved symptoms of sleep disturbance in MDD and was effective against depressive symptoms in patients experiencing high and low sleep disturbance levels. AstraZeneca funded.