P01-75 - **QUETIAPINE XR OR LITHIUM COMBINATION WITH ANTIDEPRESSANTS IN TREATMENT RESISTANT DEPRESSION**

S. Montgomery[1], L. Dell'Osso[2], S. Kasper[3], W. Pitchot[4], E. Dencker-Vansvik[5], J. Köhler[6], L. Jörgensen[5], M. Bauer[7]

[1]Imperial College School of Medicine, University of London, London, UK, [2]Psychiatry Unit, Department of Psychiatry, Neurobiology, Pisa, Italy, [3]Department of Psychiatry and Psychotherapy, Medical University of Vienna, Vienna, Austria, [4]Psychiatric Unit, University of Liège, Liège, Belgium, [5]AstraZeneca, Södertälje, Sweden, [6]AstraZeneca, Wedel, [7]Department of Psychiatry and Psychotherapy, Universitätsklinikum Carl Gustav Carus, Technische Universität, Dresden, Germany

Objectives: Compare quetiapine+antidepressant (AD) with lithium+AD, and quetiapine monotherapy with lithium+AD in open, rater-blinded treatment.

Methods: Patients with treatment resistant depression (Thase et al 1997 stage 1 and 2) with severity of MADRS ≥25 received: quetiapine XR 300mg/day plus AD (SSRIs or venlafaxine) (n=229), lithium (monitored to between 0.6 to 1.0 meq/l) plus AD (n=221) or quetiapine XR alone (300mg/day) (n=225) for 6 weeks. Primary efficacy measure was change from baseline in MADRS total score. The pre-specified non-inferiority limit was 3 points on the MADRS.

Results: Fewer patients discontinued on quetiapine+AD (15.2%) than lithium+AD (20.5%) and quetiapine monotherapy (21.5%). Quetiapine+AD and quetiapine monotherapy, were not inferior to lithium+AD in the primary (per protocol) analysis with a mean difference (97.5%CI) on the MADRS of -2.32 (-4.6 to -0.05) favouring add-on quetiapine and -0.97 (-3.24 to 1.31) favouring quetiapine monotherapy. This mandated superiority testing on the modified ITT population showing no significant difference at endpoint.

In a post hoc analysis discounting multiplicity, quetiapine+AD was significantly more effective than lithium+AD on the MADRS change from baseline, p=0.046. The advantage was observed at day 4 (p=0.007) and persisted throughout. Efficacy was supported by CGI-I (p=0.07). Quetiapine+AD showed a numerically greater advantage over lithium+AD in those with two failed treatments (Stage 2) rather than one (Stage 1).

Conclusions: Quetiapine+AD and quetiapine monotherapy, were non-inferior to lithium+AD in treatment resistant depression. There was an early significant and persistent efficacy advantage on MADRS for quetiapine augmentation compared with lithium augmentation of SSRI or venlafaxine treatment.

https://doi.org/10.1016/S0924-9338(10)70294-7 Published online by Cambridge University Press