P01-38 - EFFICACY OF ADJUNCTIVE ARIPIPRAZOLE IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER: POOLED ANALYSIS OF SUBGROUP DATA FROM THREE CLINICAL TRIALS

R. Gismondi¹, R. McQuade², J.-Y. Loze³, R. Owen⁴, R. Berman⁴

¹Bristol-Myers Squibb Company, Rome, Italy, ²Otsuka Pharmaceutical Development & Commercialization Inc, Princetown, NJ, USA, ³Otsuka Pharmaceutical, Paris, France, ⁴Bristol-Myers Squibb, Wallingford, CT, USA

Aims: To conduct a subgroup analysis of the efficacy of adjunctive aripiprazole as treatment in patients with major depressive disorder (MDD) who demonstrated an inadequate response to standard antidepressant therapy (ADT).

Methods: Data were pooled from three identical, short-term, double-blind, placebo-controlled studies (CN138-139, CN138-163, CN138-165) with an 8-week phase of placebo plus ADT and a 6-week double-blind phase with ADT plus adjunctive placebo or aripiprazole. Only MDD patients without psychotic features were eligible for entry. The primary efficacy endpoint was the mean change in the Montgomery Asberg Depression Rating Scale (MADRS) total score in the double-blind phase. Subgroup analyses of the primary efficacy endpoint were performed for age, race, ethnicity, MADRS response, number and choice of previous ADTs, episode duration, and use of selective serotonin re-uptake inhibitors (SSRI).

Results: Compared with the adjunctive placebo group, adjunctive aripiprazole was associated with greater reductions in MADRS total score in all subgroups. Mean change in MADRS total score ranged from -10.71 to -5.89 with adjunctive aripiprazole and -7.57 to -4.10 with adjunctive placebo. No statistically significant treatment-by-subgroup interaction effects were observed for any subgroup except gender (p=0.039). This difference is, however, primarily because of results from study CN138-139 results; consistent results between men and women were reported in CN138-163 and CN138-165.

Conclusions: Pooled data indicate that in patient populations with similar baseline characteristics, treatment with adjunctive aripiprazole and ADT is efficacious in improving the symptoms of MDD in subgroups of patients having an inadequate response to ADT.