

**P01-39 - ADJUNCTIVE ARIPIPRAZOLE IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER: EFFICACY DATA FROM THREE SHORT-TERM STUDIES**

**R. Gismondi**<sup>1</sup>, R. McQuade<sup>2</sup>, J.-Y. Loze<sup>3</sup>, R. Owen<sup>4</sup>, R. Marcus<sup>4</sup>

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

**Aims:** To evaluate the efficacy of aripiprazole as adjunctive treatment in patients with major depressive disorder (MDD) without psychotic features and an inadequate response to standard antidepressant therapy (ADT).

**Methods:** Data were collected from three identical, short-term, double-blind, placebo-controlled studies (CN138-139, CN138-163, CN138-165). After a single-blind prospective phase with placebo plus ADT, patients with inadequate response were randomized to 6-weeks' treatment with adjunctive aripiprazole or placebo. The primary efficacy endpoint was the mean change in the Montgomery Asberg Depression Rating Scale (MADRS) total score during the double-blind phase. Secondary endpoints were response ( $\geq 50\%$  reduction in MADRS total score), remission (MADRS total score  $\leq 10$  and  $\geq 50\%$  reduction in MADRS total score), and mean change in Hamilton Depression Rating Scale (HAM-D17) total score.

**Results:** In all three studies, adjunctive aripiprazole was associated with a significantly greater reduction in MADRS total score than adjunctive placebo, with a treatment difference ranging between -3.73 and -2.84 ( $p \leq 0.001$  in each study). Response and remission rates with adjunctive aripiprazole (32.4-46.6% and 25.4-36.8%, respectively) were also significantly higher than with adjunctive placebo (17.4-26.6% [ $p < 0.05$  in each study] and 15.2-18.9% [ $p < 0.05$  in each study]). Mean change in HAM-D17 total score ranged from -7.64 to -6.77 with adjunctive aripiprazole and from -5.12 to -4.41 with adjunctive placebo ( $p < 0.001$  for each study).

**Conclusions:** Results of the three studies indicate that treatment with adjunctive aripiprazole and ADT is effective in improving the symptoms of MDD in patients who have had an inadequate response to ADT.