

**PW01-11 - EFFECT OF ADJUNCTIVE ARIPIPRAZOLE ON QUALITY OF LIFE IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER: POOLED DATA FROM THREE CLINICAL TRIALS**

**R. Gismondi**<sup>1</sup>, J.-Y. Loze<sup>2</sup>, R. Baker<sup>3</sup>, Y. Jing<sup>3</sup>, P. Corey-Lisle<sup>4</sup>, L. Rollin<sup>4</sup>, Q.-V. Tran<sup>5</sup>, R. Forbes<sup>5</sup>, R. Berman<sup>4</sup>

<sup>1</sup>*Bristol-Myers Squibb, Rome, Italy*, <sup>2</sup>*Otsuka Pharmaceutical, Paris, France*, <sup>3</sup>*Bristol-Myers Squibb, Plainsboro, NJ*, <sup>4</sup>*Bristol-Myers Squibb, Wallingford, CT*, <sup>5</sup>*Otsuka Pharmaceutical America Pharmaceutical Inc, Rockville, MD, USA*

**Introduction:** Assessing impact of treatment from the patient perspective provides additional information about treatment efficacy in major depressive disorder (MDD) trials.

**Objectives:** Pooled data from three identically designed clinical trials showed aripiprazole adjunctive to antidepressant therapy (ADT) was effective in treating MDD.<sup>1</sup>

**Methods:** Patients who completed an 8-week prospective ADT phase with inadequate response were randomized double-blind to 6-weeks adjunctive treatment with aripiprazole or placebo. The Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form (Q-LES-Q-SF) is a 16-item, self-report measure to evaluate daily functioning, with higher scores indicating better satisfaction. Comparisons of mean change from baseline (Week 8) to Week 14 in Q-LES-Q-SF items and general subscores were performed using ANCOVA (LOCF).

**Results:** There was significant improvement in the Q-LES-Q-SF Overall-General subscore (total of items 1-14 expressed as a percentage of the maximum possible score) in the aripiprazole-treatment group (9.49% [n=507]) vs placebo (5.71% [n=492] p< 0.001). Placebo was significantly higher than aripiprazole in Physical Ability (placebo 0.13 vs aripiprazole 0.02, p=0.020). Aripiprazole was significantly higher than placebo in all other items except Physical Health and Vision. Aripiprazole also produced significant increases in both the Satisfaction with Medication (Item 15) (aripiprazole 0.36 vs placebo 0.20, p< 0.01) and Overall Satisfaction (Item 16) (aripiprazole 0.61 vs placebo 0.35, p< 0.001) scores.

**Conclusions:** Results emphasize that assessment of patient functioning and quality of life may have utility both in clinical trials and clinical practice.<sup>2</sup>

1. Berman RM, et al. *CNS Spectr*. 2009;14:197-206.
2. Wisniewski SR, et al. *J Nerv Ment Dis*. 2007;195(3):219-225.