P01-57 - **ANALYSIS OF POOLED SAFETY DATA FROM THREE RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDIESOF ADJUNCTIVE ARIPIPRAZOLE IN MAJOR DEPRESSIVE DISORDER**

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Purpose: To evaluate the safety of aripiprazole as adjunctive treatment in major depressive disorder (MDD) without psychotic features within different patient subgroups.

Methods: Data were pooled from three multicentre, randomized, double-blind, placebo-controlled studies (CN138-139, CN138-163 and CN138-165). Patients who did not respond adequately to an 8-week course of standard ADT were randomized to receive adjunctive aripiprazole or placebo for a further 6 weeks. To assess differences in the adverse events (AE) profile of aripiprazole for demographic subgroups, the incidence of AEs was presented for the pooled placebo-controlled MDD studies by gender, age, and race. An odds ratio (OR) estimate was calculated and the ORs compared across all categories using the Breslow-Day test for AEs with incidence ≥5% in the pooled aripiprazole group.

Results: In total, 14.3% of aripiprazole-treated patients and 12.5% of placebo-treated patients discontinued treatment. Treatment-emergent AEs were reported by 65.4% and 82.3% in the adjunctive placebo and adjunctive aripiprazole groups, respectively. Most aripiprazole-related AEs were, however, mild to moderate in severity. With the exception of blurred vision, which occurred in white patients only (p=0.002), there were no significant differences in the incidence of treatment-emergent AEs across different age groups, racial groups or between the genders in the aripiprazole- and placebo-treated groups.

Conclusion: Adjunctive aripiprazole was generally well tolerated and most treatment-emergent AEs were of mild to moderate severity. The AEs profile of adjunctive aripiprazole did not show significant variation in relation to age, gender or race, compared with that of placebo.

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