PW01-20 - **ADJUNCTIVE ARIPIPRAZOLE IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER: POOLED SAFETY AND TOLERABILITY DATA FROM THREE SHORT-TERM STUDIES**

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Objectives: The safety and tolerability of aripiprazole as adjunctive treatment was examined in patients with major depressive disorder (MDD) without psychotic features who had a major depressive episode and who did not respond adequately to standard antidepressant therapy (ADT).

Methods: Data from three identical short-term, double-blind, placebo-controlled studies (CN138139, CN138163, CN138165) were pooled. After a prospective phase with placebo plus ADT, patients without adequate response entered a 6-week, double-blind phase with placebo or aripiprazole plus ADT. Safety endpoints included death, serious adverse events (SAEs), treatment-emergent adverse events (AEs), Simpson-Angus Scale (SAS), Barnes Akathisia Global Clinical Assessment, Abnormal Involuntary Movement Scale (AIMS), clinical laboratory tests, vital signs and electrocardiograms.

Results: In total, 538 patients were randomized to adjunctive placebo and 547 to adjunctive aripiprazole. AEs with an incidence ≥5% and at least twice the rate of placebo were akathisia (adjunctive aripiprazole, 22.7%; adjunctive placebo, 4.1%), restlessness (12.4% vs 2.2%), fatigue (8.6% vs 4.3%), insomnia (8.2% vs 3.2%), vision blurred (6.2% vs 1.5%), somnolence (5.9% vs 2.6%), and constipation (4.9% vs 2.4%). AEs that had a treatment difference of ≥2% included akathisia, somnolence, sedation, dizziness, disturbance in attention, extrapyramidal disorder, restlessness, insomnia, constipation, dyspepsia, fatigue, feeling jittery, vision blurred, weight increased, and dyspnea. SAEs occurred in 0.7% of patients in each treatment group. There were no deaths during the studies.

Conclusions: In this pooled analysis of patients with MDD and an inadequate response to ADT, adjunctive aripiprazole showed consistently high study completion rates and low discontinuation rates resulting from adverse events.

https://doi.org/10.1016/S0924-9338(10)71422-X Published online by Cambridge University Press