

PSYCHOSOCIAL AND OVERALL EFFECTIVENESS OF ARIPIPRAZOLE ONCE-MONTHLY VS. PLACEBO ONCE-MONTHLY FOR MAINTENANCE TREATMENT IN SCHIZOPHRENIA

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Objective: Evaluate the effectiveness of investigational aripiprazole once-monthly (ARI-OM) for maintenance treatment in schizophrenia.

Methods: Detailed methodology has been published previously¹. Briefly, the study consisted of 4 phases: oral conversion to aripiprazole (Phase 1); oral aripiprazole stabilization (Phase 2); ARI-OM stabilization (Phase 3), with co-administration of oral aripiprazole for the first 2 weeks; and an ARI-OM maintenance phase (Phase 4). Effectiveness assessments included Investigator's Assessment Questionnaire (IAQ) scores, a scale that evaluates effectiveness of current treatment vs. pre-trial medication, where a negative change in score signals improvement, and Personal and Social Performance (PSP) scale scores, where negative change in score signals worsening.

Results: 710 patients entered Phase 2, 576 Phase 3 and 403 Phase 4 (ARI-OM=269, placebo once-monthly [placebo-OM]=134). Mean IAQ Total scores remained stable in Phase 2 (31.3) and Phase 3 (30.6). During Phase 4, the mean change in IAQ Total score was +1.3 for ARI-OM vs. +3.8 for placebo-OM ($p < 0.0001$). Mean changes in PSP Total scale scores showed improvement during Phase 2 (3.0) and Phase 3 (2.6). Mean change in PSP scores during Phase 4 showed greater functional stability with ARI-OM (-1.7) compared with placebo-OM (-6.2) ($p = 0.0002$ vs. placebo-OM).

Conclusions: Improvements in effectiveness, as assessed by the IAQ and PSP Total scale scores, in the Phases 2 & 3 were maintained in Phase 4 for ARI-OM compared with placebo-OM. Treatment with ARI-OM improved symptoms, overall response to treatment and functioning.

1. Kane J, et al. *J.Clin.Psychiatry* 2012;73:617-624.