Article: 2277
Topic: 69 - Schizophrenia

A PLACEBO-CONTROLLED STUDY OF EFFICACY AND SAFETY OF ARIPIPRAZOLE ONCE-MONTHLY FOR LONG-TERM MAINTENANCE TREATMENT IN SCHIZOPHRENIA

A. Eramo[1], *W.W. Fleischhacker*[2], *R. Sanchez*[3], *P. Perry*[3], *N. Jin*[4], *B. Johnson*[3], *R.D. McQuade*[3], *W.H. Carson*[3], *J. Kane*[5,6]

[1]Lundbeck LLC, Deerfield, IL, USA, [2]Department of Psychiatry and Psychotherapy, Medical University Innsbruck, Innsbruck, Austria, [3]Otsuka Pharmaceutical Development & Commercialization, Inc., Princeton, NJ, [4]Otsuka Pharmaceutical Development & Commercialization, Inc., Rockville, MD, [5]The Zucker Hillside Hospital, Glen Oaks, [6]Hofstra North Shore-LIJ School of Medicine, Hempstead, NY, USA

Objective: Evaluate the efficacy and long-term safety of investigational aripiprazole once-monthly (ARI-OM) for maintenance treatment in schizophrenia.
Methods: Patients requiring chronic treatment for schizophrenia, not on aripiprazole monotherapy, were cross-titrated from other antipsychotic(s) to aripiprazole in an oral conversion phase (Phase 1). All patients entered an oral aripiprazole stabilization phase (Phase 2). Patients meeting stability criteria entered an ARI-OM stabilization phase (Phase 3), with co-administration of oral aripiprazole for the first 2 weeks. Patients meeting stability criteria were randomized to ARI-OM or placebo once-monthly (placebo-OM) during a 52-week, double-blind maintenance phase (Phase 4). Primary endpoint was time-to-impending relapse. Safety and tolerability were also assessed.
Results: 710 patients entered Phase 2, 576 Phase 3 and 403 Phase 4 (ARI-OM=269, placebo-OM=134). The study was terminated early because efficacy was demonstrated by a pre-planned interim analysis. Time-to-impending relapse was significantly delayed with ARI-OM vs. placebo-OM ($p< 0.0001$, log-rank test). Discontinuations due to treatment-emergent adverse events (AEs) were: Phase 1, 3.8% (n=24/632); Phase 2, 3.0% (n=21/709); Phase 3, 4.9% (n=28/576); Phase 4, 7.1% (n=19/269). Most AEs were mild or moderate. Insomnia was the only AE >5% incidence in any phase. Headache, somnolence, and nausea had a peak first onset within the first 4 weeks of treatment. There were no unusual shifts in all phases in laboratory values, fasting metabolic parameters, weight, or objective scales of movement disorders.
Conclusions: ARI-OM significantly delayed time-to-impending relapse compared with placebo-OM and was well tolerated as maintenance treatment in schizophrenia[1].
1. Kane J, et al. J.Clin.Psychiatry 2012;73:617-624.

https://doi.org/10.1016/S0924-9338(13)77138-4 Published online by Cambridge University Press