Article: 2283
Topic: 69 - Schizophrenia

SAFETY AND TOLERABILITY OF ARIPIPRAZOLE ONCE-MONTHLY INITIATED IN ADULTS WITH SCHIZOPHRENIA STABILIZED ON ATYPICAL ORAL ANTIPSYCHOTICS OTHER THAN ARIPIPRAZOLE

S. Potkin[1], *A. Raoufinia*[2], *S. Mallikaarjun*[2], *P. Bricmont*[2], *T. Peters-Strickland*[3], *W. Kasper*[3], *N. Jin*[2], *R.A. Baker*[3], *A. Eramo*[4], *R. Sanchez*[3], *R.D. McQuade*[3]

[1]Department of Psychiatry and Human Behavior, University of California, Irvine, CA, [2]Otsuka Pharmaceutical Development & Commercialization, Inc., Rockville, MD, [3]Otsuka Pharmaceutical Development & Commercialization, Inc., Princeton, NJ, USA, [4]H. Lundbeck A/S, Valby, Denmark

Objective: Evaluate the safety and tolerability of aripiprazole once-monthly (ARI-OM) initiation in patients stabilized on oral antipsychotics other than aripiprazole. Previous pivotal Phase III trials have evaluated initiating ARI-OM in patients stabilized on oral aripiprazole[1].

Methods: Eligible patients were treated with oral atypical antipsychotics other than aripiprazole with a history of oral aripiprazole tolerability. The study included a screening phase (30 days) and a treatment phase (28 days). Patients were stabilized per investigator's judgment for ≥14 days on risperidone, olanzapine, quetiapine, or ziprasidone, before administration of ARI-OM (400 mg). Current oral antipsychotic was co-administered with ARI-OM for 2 weeks to determine safety and tolerability of a single ARI-OM dose following treatment initiation. Safety assessments were adverse events (AEs); extrapyramidal symptoms (EPSs) using standard objective rating scales; Columbia-Suicide Severity Rating Scale; clinical laboratory measures; and weight changes.

Results: 60 patients initiated ARI-OM, while continuing treatment for ≤2 weeks with oral risperidone (n=24), quetiapine (n=28), ziprasidone (n=5) or olanzapine (n=3). Treatment-emergent (TE) AEs (≥5%) were fatigue, injection-site pain, and restlessness (risperidone); insomnia, dystonia, injection-site pain, and toothache (quetiapine); and muscle spasm, tooth abscess, and toothache (ziprasidone). Prior olanzapine did not cause any AEs. Incidence of TE-EPSs were similar in all groups (< 5%). There were no unusual changes in objective EPS rating scales, suicidality, weight, laboratory values or fasting metabolic parameters across all groups.

Conclusions: The AE profile of patients receiving ARI-OM concomitant with oral atypical antipsychotics other than aripiprazole was consistent with prior reports[1].

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

https://doi.org/10.1016/S0924-9338(13)77143-8 Published online by Cambridge University Press