

## LONG-ACTING INJECTABLE ANTIPSYCHOTICS IN THE TREATMENT OF SCHIZOPHRENIA

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The nature of schizophrenia gives rise to a number of unmet needs that go beyond proven efficacy and safety of pharmacotherapy in randomized clinical trials (RCTs). Long-acting injectable (LAI) formulations of new generation antipsychotics offer an alternative treatment choice, and the investigational formulation of aripiprazole once-monthly is under regulatory review in the both the US and EU for maintenance treatment of schizophrenia.

The efficacy of aripiprazole tablets in the treatment of schizophrenia has been well established, with consistently low relapse rates, good tolerability, and preservation of function. In the “ASPIRE US” (Aripiprazole-Intramuscular-Depot Program in Schizophrenia) trial, a 52-week, multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of aripiprazole once-monthly as maintenance treatment in patients with schizophrenia, aripiprazole once-monthly significantly delayed the time to impending relapse compared with placebo in the long-term maintenance treatment for schizophrenia. At 52 weeks, 10% of patients in the aripiprazole once-monthly group had relapsed, compared with 39.9% of patients in the placebo group (Hazard ratio, 5.03,  $p < 0.0001$ ).<sup>1</sup> In a second study comparing aripiprazole once-monthly with oral aripiprazole,<sup>2</sup> aripiprazole once-monthly was non-inferior to oral aripiprazole and significantly delayed time to exacerbation of psychotic symptoms/impending relapse compared with aripiprazole once-monthly at a sub-threshold therapeutic dose. The estimated relapse rates at Week 26 were 7.1% for aripiprazole once-monthly and 7.8% for oral aripiprazole. This presentation will review the available evidence from recent RCTs showing the efficacy and safety of aripiprazole once-monthly for the long-term management of schizophrenia, and to explore, the link between low relapse rates and functional preservation.

### References

1. Kane JM et al. Aripiprazole intramuscular depot as maintenance treatment in patients with schizophrenia: a 52-week, multicenter, randomized, double-blind, placebo-controlled study. *J Clin Psychiatry* 2012;**73**:617-624.
2. Fleischhacker WW et al. Presented at the 51st Annual Meeting of the American College of Neuropsychopharmacology (ACNP), Hollywood, FL, USA, 2-6 December 2012 (unpublished).