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A DOUBLE-BLIND, PLACEBO-CONTROLLED, RANDOMIZED WITHDRAWAL STUDY OF LURASIDONE FOR THE MAINTENANCE OF EFFICACY IN PATIENTS WITH SCHIZOPHRENIA

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Introduction: Schizophrenia is a chronic disease; consequently, long-term maintenance of efficacy is an important clinical goal.

Objective: To evaluate lurasidone as maintenance treatment for schizophrenia.

Aims: To demonstrate maintenance of efficacy with lurasidone.

Methods: Adult patients experiencing an acute exacerbation of schizophrenia received 12-24 weeks of open-label treatment with lurasidone (40-80 mg/d, flexibly dosed). Those who maintained clinical stability for ≥12 weeks were randomized to placebo or lurasidone (40-80 mg/d, flexibly dosed) and entered the 28-week, double-blind withdrawal phase.

Results: Of 676 enrolled patients, 285 met protocol-specified stabilization criteria and were randomized to lurasidone (N=144) or placebo (N=141). Relapse occurred in a greater proportion of patients receiving placebo (41.1%) than lurasidone (29.9%). Time to relapse based on Kaplan-Meier survival analysis was significantly longer for lurasidone compared with placebo (log-rank test, p=0.039). Lurasidone was associated with a 33.7% reduction in risk of relapse versus placebo (Cox hazard ratio [95% confidence interval], 0.663 [0.447, 0.983]; p=0.041). Patients receiving placebo demonstrated significantly greater worsening on PANSS and CGI-S scores compared to lurasidone-treated patients (PANSS mean change, +12.4 vs +8.3, p=0.029; CGI-S mean change, +0.7 vs +0.4, p=0.015; ANCOVA-LOCF). The discontinuation rate due to adverse events was 13.9% for lurasidone and 15.6% for placebo. Minimal changes in weight, prolactin, lipid, and glucose parameters were observed.

Conclusion: This study demonstrated the efficacy of lurasidone for the maintenance treatment of patients with schizophrenia. Lurasidone was generally well tolerated, with minimal effects on weight and other metabolic parameters.

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