

LURASIDONE IN THE TREATMENT OF EARLY-STAGE SCHIZOPHRENIA: A POST-HOC ANALYSIS OF THREE POOLED ACUTE TREATMENT STUDIES

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Introduction: Lurasidone has demonstrated efficacy treating adults with schizophrenia, the majority of them with chronic, multi-episode schizophrenia.

Objective: To assess baseline characteristics and evaluate efficacy of lurasidone in patients with early-stage schizophrenia (ESS).

Aims: Evaluate efficacy of lurasidone in patients with ESS.

Methods: A pooled analysis of patients with ESS (defined as onset of illness within 3 years of study entry) from three, 6-week, randomized, placebo-controlled, phase 3 trials was performed. Additional analysis was conducted for patients with onset within 5 years. Efficacy was evaluated using a mixed-model repeated-measures analysis of change in PANSS total score and CGI-Severity score. Treatment response was defined as $\geq 20\%$ improvement in PANSS total score from baseline.

Results: 857 subjects were randomized to lurasidone and 366 to placebo of which 102(11.9%) lurasidone and 44(12.0%) placebo subjects had ESS (onset within 3 years). Among 146 ESS subjects, 70.5% were male, mean age was 28.6 years. Baseline PANSS total and CGI-S scores were 96.8 and 5.0 respectively. Lurasidone treatment of early-stage schizophrenia subjects showed significant improvement vs placebo in PANSS total score (-25.9 vs -17.3; $p < 0.05$, effect size=0.42), PANSS positive (-9.6 vs 6.0; $p < 0.01$) and negative (-5.6 vs -3.2; $p = 0.014$) subscale scores, and improvement in CGI-S score (-1.7 vs -1.3; $p = 0.089$, effect size=0.36). Responder rates were 69% for lurasidone vs 48% for placebo (NNT=5). Similar results were observed in subjects with within 5 years of onset of illness.

Conclusion: In this subgroup analysis, lurasidone was effective in the treatment of patients with early-stage schizophrenia.