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LONG-TERM SAFETY AND EFFECTIVENESS OF LURASIDONE IN SCHIZOPHRENIA: RESULTS OF A 22 MONTH, OPEN-LABEL EXTENSION STUDY

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Introduction: Lurasidone has demonstrated efficacy in the treatment of schizophrenia in a series of short-term placebo-controlled trials.

Objectives: To evaluate the safety, tolerability and effectiveness of lurasidone in the long-term treatment of patients with a DSM-IV-TR diagnosis of schizophrenia.

Methods: Patients who completed a 6 week, double-blind, placebo-controlled trial received once-daily, flexible-doses of lurasidone, 40-120 mg in a 22 month open-label extension study. An observed case analysis was performed on change from pre-treatment baseline in safety and efficacy parameters.

Results: 250 subjects entered the study; 39.8% completed 12 months and 26.8% completed 22 months of treatment. Lurasidone treatment was associated with a mean endpoint change in weight of +0.7 kg. Median endpoint change at Month 12 and Month 24, respectively, was -1.0 and -9.0 mg/dL for total cholesterol; 0.0 and -1.0 mg/dL for LDL; +1.0 and -11.0 mg/dL for triglycerides; +4.0 and +2.0 mg/dL for glucose; 0.0 and +0.1 % for HbA1c; and -1.3 and -1.1 ng/mL for prolactin. The mean PANSS total score was 69.5 at extension baseline. The mean (95% CI) endpoint change from extension baseline in PANSS total score was -0.5 (95%-CI: -0.7, -0.3). Overall, 14.7% of patients discontinued due to an adverse event. Adverse events occurring with an incidence ≥10% were schizophrenia (12.4%), akathisia (10.8%) and somnolence (10.8%).

Conclusions: In this 22 month extension study, treatment with lurasidone was associated with minimal effects on weight, glucose, and lipids. Subjects demonstrated sustained improvement in the PANSS total score for up to 24 months of lurasidone treatment.

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