Article: 1202
Topic: EPV04 - e-Poster 04: Child and Adolescent Psychiatry

Pharmacokinetic and Safety Evaluation of Lurasidone in Pediatric Patients with Psychiatric Disorders

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Introduction: Lurasidone has demonstrated efficacy for schizophrenia and bipolar depression in adults.

Objective: To identify a tolerated dose range of lurasidone for pediatric studies.

Aims: To characterize PK and tolerability profiles of lurasidone in a pediatric population.

Methods: Patients aged 6 to 17 years diagnosed with ADHD and conduct disorder/disruptive behavior disorder, bipolar disorder, schizophrenia, Tourette syndrome, or autism spectrum disorder were assigned to 1 of 5 open-label lurasidone dosing cohorts (20, 40, 80, 120, or 160 mg/d). If a dose level was tolerated, the next dose cohort was initiated. In the single-dose phase, blood was collected predose and for 48 hours postdose. In the multiple-dose phase, patients received once-daily lurasidone for 7 to 9 days; blood was collected before and for 24 hours after the final dose. Lurasidone PK parameters, including maximum serum concentration and area under the concentration-time curve, were calculated.

Results: In 105 patients, the observed lurasidone PK were consistent with a PK model of adult exposure at steady state. The most common AEs were somnolence (42%), sedation (18%), and nausea (17%); incidence of AEs was generally dose-dependent across the 20-160 mg/d dose range. All 6- to 9-year-old patients experienced somnolence at 120 mg/d. Two serious AEs (parkinsonism, dystonia) were reported, both at 80 mg/d.

Conclusions: The PK and AE profiles of lurasidone in this heterogeneous pediatric population were consistent with data observed in adult populations. Based on this study, doses of lurasidone 20-80 mg/d are selected for evaluation in pediatric clinical trials.

Funding: Sunovion Pharmaceuticals Inc.

https://doi.org/10.1016/S0924-9338(15)30944-5 Published online by Cambridge University Press