Efficacy and Safety of Lurasidone in Adolescents with Schizophrenia: Analysis of a 2-Year, Open-Label Extension Study

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INTRODUCTION & OBJECTIVE

- Onset of schizophrenia commonly occurs during adolescence or early adulthood, and is associated with severe symptomatology and lifelong functional impairment. Lurasidone has demonstrated efficacy and safety in the acute and long-term treatment of adults with schizophrenia in the dose range of 37.5-74 mg/day, and in the short-term treatment of adolescents with schizophrenia in the dosing range of 37.5-74 mg/day
- The aim of the current study was to evaluate the long-term safety and effectiveness of lurasidone in adolescents with schizophrenia

METHODS

Study Design
- In this 104-week extension study, patients who completed the initial 6-week, randomised, double-blind (DB), placebo-controlled study were treated, open-label (OL), with flexible doses of 18.5-74 mg/d of lurasidone
- Patients were initially treated with lurasidone 37.5 mg/d for one week, then were treated with flexible doses of lurasidone in the range of 18.5-74 mg/d

Key Study Entry Criteria
- Anzio Double-blind Study: Adolescent patients (13-17 years old) who met DSM-IV-TR criteria for a diagnosis of schizophrenia with a Positive and Negative Syndrome Scale (PANSS) total score ≥70 and <120

Efficacy and Safety Measures
- Effectiveness measures included the PANSS total and subscale scores (Positive, Negative, General Psychopathology, Excitability); CGI-S score; the Children's Global Assessment Scale (CGAS) and the Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) "normal" values within 10% of community mean score
- Responder criteria: ≥20% improvement in PANSS total score from double-blind baseline was calculated based on both observed case data, and last observation carried forward (LOCF) data, for patient groups randomised to lurasidone or placebo in the original acute treatment study
- Safety evaluations included treatment-emergent adverse events, weight (actual and expected, based on Centers for Disease Control [CDC] reference growth charts), ECG and laboratory tests

RESULTS

Table 1. Baseline Patient Characteristics (Safety Population)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Lurasidone (open-label)</th>
<th>Placebo (open-label)</th>
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</thead>
<tbody>
<tr>
<td>Baseline Total</td>
<td>93.9 ± 74.1</td>
<td>92.7 ± 79.8</td>
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<tr>
<td>PANSS Positive Score</td>
<td>23.9 ± 17.1</td>
<td>23.4 ± 19.7</td>
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<tr>
<td>PANSS Negative Score</td>
<td>24.3 ± 20.0</td>
<td>24.5 ± 21.5</td>
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DB: double-blind; OL: open-label; PANSS = Positive and Negative Syndrome Scale; CGI-S = Clinical Global Impression–Severity; PQ-LES-Q = Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire

Figure 1. Change From Double-blind Baseline in PANSS Total and Factor Scores

- The mean PANSS responder rates were 63.1% at DB Baseline, 89.3% at Week 28, 92.3% at Week 52, and 91.0% at Week 104 (Responder criteria: ≥20% improvement from double-blind baseline in PANSS total score)
- The mean change from DB baseline in the CGI-S severity score was -0.83 at OL baseline, -1.87 at week 52, and -2.04 at week 104
- The mean CGI-S total score was 4.47 at DB baseline, 5.00 at OL baseline, 6.88 at week 52, and 7.18 at week 104
- The mean PQ-LES-Q total score was 52.2 at DB baseline, 57.1 at OL baseline, 66.5 at week 52, and 66.8 at week 104

DISCLOSURES

Drs. Goldman, Tocco, Pikalov, Deng, and Loebel are employees of Sunovion Pharmaceuticals Inc.

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CONCLUSIONS

- In this open-label extension study of adolescents with schizophrenia, up to 2 years of treatment with lurasidone (18.5-74 mg/d) was associated with continued improvement in schizophrenia symptoms as measured by the PANSS total and subscale scores, as well as continued improvement in measures of functioning and quality of life
- Lurasidone was generally well-tolerated, with minimal changes in weight, metabolic parameters, and prolactin. The most common adverse events were headache, nausea, and anxiety

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