

**Introduction:** Compared with adult onset, early onset schizophrenia is typically characterized by greater illness severity and less favorable prognosis.

**Objectives:** To evaluate the proportion of adolescent patients with schizophrenia who achieved sustained remission and recovery during 2 years of treatment with lurasidone.

**Methods:** Patients aged 13-17 years with a DSM-IV-TR diagnosis of schizophrenia, and a Positive and Negative Symptom Scale (PANSS) total score  $\geq 70$  and  $< 120$ , were randomized to 6 weeks of double-blind (DB), fixed-dose treatment with lurasidone (37 or 74 mg/d) or placebo. Patients who completed 6 weeks of DB treatment were eligible to enroll in a 2-year, open-label (OL), flexible dose extension study of lurasidone (18.5-74 mg/d). Criteria for sustained remission, were the 6-month consensus criteria summarized by Andreasen (Am J Psych 2005;162:441-9). Criteria for sustained recovery consisted of meeting sustained remission criteria with a Children's Global Assessment Scale (CGAS) score  $\geq 70$  for at least 6-months indicating no clinically significant functional impairment.

**Results:** A total of 271 patients completed the 6-week DB study and entered the extension study, and 186 (68.6%) and 156 (57.6%) completed 52 weeks and 104 weeks of treatment, respectively. During OL treatment with lurasidone, 52.8% met sustained remission criteria, with a Kaplan-Meier (KM) estimate of 64.1 weeks for median time to sustained remission; and 28.8% met sustained recovery criteria, KM estimate of 104.6 weeks for median time to sustained recovery.

**Conclusions:** For adolescents with schizophrenia, treatment with lurasidone was associated with high rates of sustained remission and sustained recovery over a two-year period.

**Disclosure:** Employee of Sunovion Pharmaceuticals Inc. The study summarized in this Abstract was supported by funding from Sunovion Pharmaceuticals Inc

**Keywords:** lurasidone; remission; schizophrénia; adolescence

## O269

### Efficacy and safety of lurasidone in adolescents and young adults with schizophrenia: Pooled analysis of double-blind, placebo-controlled 6-week studies

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**Introduction:** Onset of schizophrenia commonly occurs during late adolescence or early adulthood and is often characterized by greater symptom severity and impairment.

**Objectives:** To evaluate the efficacy and safety of lurasidone in the treatment of acute schizophrenia in adolescents and young adults.

**Methods:** The 4 studies in this pooled analysis used similar study designs. Patients (ages 13-25 years) were randomized to 6 weeks of double-blind, placebo-controlled treatment with once-daily lurasidone (37 mg, 74 mg, 111 mg, 148 mg). The primary outcome was

endpoint change in the Positive and Negative Syndrome Scale (PANSS) total score; secondary measures included the Clinical Global Impression, Severity scale (CGI-S).

**Results:** The safety population consisted of 537 patients; 79.1% completed the studies. Treatment with lurasidone was significant ( $P < 0.001$ ) at Week 6 endpoint for change in the PANSS total score, with higher effect sizes (ES) at higher doses (37 mg, 0.53; 74 mg, 0.57; 111 mg, 0.67; 148 mg, 1.35); significance was also observed for change in the CGI-S (37 mg, 0.51; 74 mg, 0.49; 111 mg, 0.57; 148 mg, 1.75). For lurasidone (combined doses), 3 adverse events occurred with a frequency  $\geq 5\%$  (nausea, 13.5%; somnolence, 12.1%; akathisia, 10.1%); 4.8% of patients discontinued due to an adverse event. At LOCF-endpoint, 3.6% of patients had weight gain  $\geq 7\%$ , and 1.5% had weight loss  $\geq 7\%$ . Minimal median changes were observed at endpoint in metabolic lab values.

**Conclusions:** In adolescents and young adults with schizophrenia, treatment with lurasidone in doses of 37-148 mg/d was a safe, well-tolerated, and effective treatment.

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**Keywords:** schizophrénia; adolescent; lurasidone

## O270

### The differential impact of severe childhood trauma on emotion recognition in males and females with first-episode psychosis

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**Introduction:** Childhood trauma increases social functioning deficits, which in turn negatively impact social inclusion in those experiencing first-episode psychosis (FEP). Associations between aberrant higher-order social cognitive processes such as emotion recognition (ER) and trauma severity may be one pathway by which trauma negatively impacts social functioning.

**Objectives:** Given sex differences identified in the experience of childhood trauma, it is pertinent to evaluate how trauma severity may differentially impact ER in males and females.

**Methods:** Eighty-three FEP participants (52 males, 31 females) and 69 nonclinical controls (49 males, 20 females) completed the Cog-State Research Battery. FEP participants completed the Childhood Trauma Questionnaire. A sex  $\times$  group (FEP, controls) ANOVA examined ER differences and was followed by two-way ANCOVAs investigating the effects of sex and childhood trauma severity (none, low, moderate, severe) on ER and global cognition in FEP.

**Results:** FEP participants had significantly lower ER scores than controls ( $p = .035$ ). In FEP, a significant interaction emerged between sex and childhood trauma severity ( $F(3, 72) = 6.382, p = .001$ ), selective to ER, while controlling for age at onset. Simple effects analyses revealed that females in the severe trauma category exhibited superior ER capacity relative to males.