# Panel Majority Backs Olanzapine for Teen Use

BY ELIZABETH MECHCATIE

ADELPHI, MD. — The majority of a Food and Drug Administration advisory panel agreed that the data on the atypical antipsychotic olanzapine indicated that it was effective and had an acceptable safety profile for treating two pediatric indications: schizophrenia and bipolar mania in patients aged 13-17 years.

At a meeting of the FDA's Psychopharmacologic Drugs Advisory Committee, the panel voted 11-5, with 2 abstentions, that olanzapine had been shown to be effective as a treatment for schizophrenia in this age group, with the majority—10 panelists—voting that it had been shown to be "acceptably safe" for this indication. However, four of the panelists voted no on the safety question and four abstained, citing concerns that included the well-known metabolic effects of olanzapine.

The panel also voted 17- 0, with 1 abstention, that the drug had been shown to be effective for treating bipolar mania, and voted 11-4, with 3 abstentions, that it had been shown to be acceptably safe in this age group for this indication.

Those voting positively on safety and efficacy for both indications said that they considered the drug as a second-line treatment, because of its metabolic effects. If approved, the label would advise clinicians to consider drugs before this one, because of concerns over its metabolic effects, Dr. Thomas Laughren, director of the FDA's division of psychiatry products, said at the meeting.

Olanzapine is marketed as Zyprexa by Eli Lilly and Co., and is approved for treating schizophrenia and bipolar dis-



# Panel Supports Quetiapine for Pediatric Use

ADELPHI, MD. — The atypical antipsychotic quetiapine is safe and effective for treating schizophrenia in adolescents and bipolar mania in both children and adolescents between the ages of 10 and 17 years, according to a Food and Drug Administration advisory panel.

At a meeting in June, the FDA's Psychopharmacologic Drugs Advisory Committee voted 17-1 that data on quetiapine showed it was effective for treating schizophrenia in adolescents aged 13-17 years. The panel also voted 16-0, with 2 abstentions, that the drug was "acceptably safe" for treating schizophrenia in this population.

The panel voted 17-0, with 1 abstention, that the drug was effective in treating bipolar mania in children and adolescents aged 10-17 years, and voted 13-0, with 5 abstentions, that it was safe in this group. A concern among those abstaining was safety in children aged 10-12.

The FDA usually follows the recommendations of its advisory panels.

Quetiapine is marketed as Seroquel by AstraZeneca Pharmaceuticals LP. The company presented results of three studies: two short-term studies and a safety study that followed 505 of these patients for 6 months.

One study compared 400 mg or 600 mg of quetiapine per day with placebo in 284 patients aged 10-17 years who had bipolar I mania. The patients were treated for 3 weeks. Changes in the Young Mania Rating Scale from baseline to day 21, the primary efficacy end point, were significantly greater in those on quetiapine than in those on placebo.

The second study comprised 222 patients aged 13-17 years, who had schizophrenia and were treated with 400 mg or 800 mg per day of quetiapine or placebo for 6 weeks. Changes in the Positive and Negative Syndrome Scale, which measures the severity of different components of schizophrenia, were significantly greater in those taking quetiapine.

In the two short-term studies, somnolence was the most common adverse event, affecting almost half of the patients on quetiapine and lasting for a mean of 12 days.

**—Elizabeth Mechcatie**