# Modafinil Safe and Effective for Pediatric ADHD

BY MICHELE G. SULLIVAN
*Mid-Atlantic Bureau*

TORONTO — Modafinil is safe and effective in treating pediatric attention-deficit hyperactivity disorder. Symptom scores were twice as high as placebo, according to two posters presented at the joint annual meeting of the American Academy of Child and Adolescent Psychiatry and the Canadian Academy of Child and Adolescent Psychiatry.

The posters, sponsored by Cephalon Inc., concluded that children tolerated the film-coated tablets well in dosages of up to 425 mg/day. Insomnia, headache, and decreased appetite were the most commonly reported adverse events. Those adverse events typically occurred during the first 2 weeks of therapy and decreased thereafter, said Dr. Christopher Kratochvil of the University of Nebraska.

The posters analyzed three multicenter, double-blind studies that included a total of 633 children aged 6-17 years. Two studies were identical 9-week flexible-dosing trials. The third was a 7-week, fixed-dose, placebo-controlled study (340 or 425 mg/day), followed by a 2-week period in which half the modafinil group was switched to placebo without tapering while the other half continued modafinil treatment.

Adverse events were more common in the active group than the placebo group and included insomnia (27% vs. 4%), headache (20% vs. 13%), and decreased appetite (16% vs. 3%).

The adverse events were all classified as mild to moderate. They peaked in the first 2 weeks of treatment and subsequently subsided. No apparent association was found between adverse events and dosage.

There were no significant changes in heart rate or blood pressure between the groups, and the abrupt discontinuation of the drug did not lead to acute withdrawal symptoms or rebound effects.

The drug effectively reduced the symptoms of ADHD, especially hyperactivity and inattention, reported Dr. Joseph Biederman of Massachusetts General Hospital. Effects were consistent whether assessed by physician, parent, or teacher. Physicians assessed almost 50% of the active groups as much improved at the end of treatment, vs. 20% of the placebo group. ■

# Atomoxetine, Methylphenidate Aid in ADHD

TORONTO — Atomoxetine once a day is as effective as methylphenidate taken twice a day in reducing symptoms of attention-deficit hyperactivity disorder in children, Dr. Yufeng Wang of Beijing Medical University reported in a poster at the joint annual meeting of the American Academy of Child and Adolescent Psychiatry and the Canadian Academy of Child and Adolescent Psychiatry.

However, the study, funded by Eli Lilly & Co., concluded that treatment-emergent adverse events, including anorexia, nausea, somnolence, dizziness, and vomiting, were significantly more common among those taking atomoxetine.

The study involved a total of 330 children aged 6-16 years from China, Mexico, and Korea who were randomized to either once-daily atomoxetine (0.8-1.8 mg/kg per day) or twice-daily methylphenidate (0.2-0.5 mg/kg per day). Responders were those who experienced at least a 40% reduction from baseline symptom scores as measured by the parents' ADHD Rating Scale. Response rates were 77% for atomoxetine and 81% for methylphenidate—not a statistically significant difference.

The total score changes on the parents' ADHD Rating Scale were similar for atomoxetine and methylphenidate (38 vs. 37, respectively), as were the score changes on the inattention and hyperactivity subscales. Changes on the Connors Parent Rating Scale and the Clinical Global Impressions scale also were similar for both groups.

Side effects were classified as mild to moderate, and tended to occur early and decrease over time. The side effects that were significantly more common in the atomoxetine group than in the methylphenidate group were anorexia (37% vs. 25%), decreased appetite (28% vs. 19%), nausea (20% vs. 10%), somnolence (26% vs. 4%), dizziness (15% vs. 7%), and vomiting (12% vs. 6%).

**—Michele G. Sullivan**