

## Noteworthy Briefs from the Field

### FDA APPROVES ARIPIPRAZOLE FOR TREATMENT OF IRRITABILITY ASSOCIATED WITH AUTISM IN PEDIATRIC PATIENTS

The United States Food and Drug Administration approved aripiprazole (Abilify, Otsuka Pharmaceutical Group) for the treatment of irritability associated with autism in pediatric patients. The recommended initial dose for this indication is 2 mg/day. The target and maximum doses are 5–10 mg/day and 15 mg/day, respectively.

Two 8-week, randomized, double-blind, placebo-controlled trials showed significant improvement in the irritability subscale of the Aberrant Behavior Checklist, which measures emotional and behavioral symptoms of irritability in autism spectrum disorders. Such symptoms include aggression, deliberate self-injury, tantrums, and mood lability. Subjects ranged from 6–17 years of age and received doses of aripiprazole ranging from 2–15 mg/day.

Patients in a flexible-dose study received aripiprazole 2 mg/day at onset; doses were titrated up to a maximum of 15 mg/day according to clinical response up to week 6. The mean daily dose at 8 weeks was 8.6 mg/day. Eighty-three percent and 70.6% of the aripiprazole and placebo groups, respectively, completed the flexible-dose trial.

In a fixed-dose study, patients received 2 mg/day for 1 week, thereafter receiving 5 mg/day increases at weekly intervals until reaching the desired effect. Clinically significant weight gain ( $\geq 7\%$  change from baseline) occurred in 26% of subjects receiving active treatment and in 7% of placebo patients.

The most common adverse events included sedation, fatigue, vomiting, somnolence, tremor, salivary hypersecretion, and extrapyramidal disorder.

For more information, please see the medication's full prescribing information at [www.abilify.com](http://www.abilify.com). –LS

### FDA APPROVES ZIPRASIDONE HCl CAPSULES FOR THE ADJUNCTIVE MAINTENANCE TREATMENT OF ADULT BIPOLAR I DISORDER

The US FDA approved ziprasidone HCl (Geodon, Pfizer) for the adjunctive maintenance treatment of bipolar I disorder and as an adjunct to lithium or valproate in adults. The recommended dosage for acute treatment of manic/mixed episodes of bipolar I disorder is 40 mg BID increased to 60 mg or 80 mg BID on day 2 of treatment. Subsequent dose adjustments should be based on tolerability and efficacy within the range of 40–80 mg BID. For maintenance treatment of bipolar I disorder as an adjunct to lithium or valproate, the patient should continue treatment at the same dose on which he or she was initially stabilized, within the range of 40–80 mg BID.

Approval was based on a 6-month, double-blind, randomized, placebo-controlled study of ziprasidone in adult patients with bipolar I disorder. An open-label stabilization period of 10–16 weeks was followed by randomization of 240 patients to either continue on ziprasidone plus lithium or valproate, or to have ziprasidone replaced by placebo. Time to recurrence of a mood episode requiring intervention was the primary endpoint in the study. During the 6-month treatment period, 19.7% of patients receiving ziprasidone plus lithium or valproate required intervention for a mood episode, compared to 32.4% of patients receiving placebo.

The most common adverse events included somnolence, extrapyramidal symptoms, dizziness, akathisia, and abnormal vision.

For more information, please see the medication's full prescribing information at [www.geodon.com](http://www.geodon.com). –DC

## TRANSCENDENTAL MEDITATION EFFECTS BLOOD PRESSURE, PSYCHOLOGICAL DISTRESS, AND COPING IN COLLEGE STUDENTS

Psychological distress contributes to the development of hypertension in young adults. According to a recent study by Sanford Nidich, EdD, at the Center for Natural Medicine and Prevention, at Maharishi University of Management Research Institute, and colleagues, transcendental meditation may significantly reduce blood pressure, psychological distress, and coping in at-risk college students.

In a randomized controlled trial (RCT), 298 American University students were randomly allocated to either a transcendental meditation program or wait-list control over a 3-month intervention period. The researchers similarly analyzed a subgroup of 159 students at risk for hypertension. Blood pressure, psychological distress, and coping ability were assessed at baseline and after three months.

Study results showed significant changes in systolic blood pressure (SBP)/diastolic blood pressure (DBP). For the overall sample, changes in SBP/DBP were  $-2.0/-1.2$  mm Hg for the transcendental meditation group compared to  $+0.4/+0.5$  mm Hg for controls ( $P=.15$ ,  $P=.15$ , respectively). Changes in SBP/DBP for the hypertension risk subgroup were  $-5.0/-2.8$  mm Hg for the transcendental meditation group compared to  $+1.3/+1.2$  mm Hg for controls ( $P=.014$ ,  $P=.028$ , respectively). The researchers found significant improvements in total psychological distress, anxiety, depression, anger/hostility, and coping ( $P<.05$ ). Changes in psychological distress and coping correlated with SBP ( $P<.05$ ) and DBP ( $P<.08$ ) changes.

The authors concluded that this RCT is the first to demonstrate that a transcendental meditation program can decrease blood pressure and psychological distress and increase coping in college-aged students at risk of hypertension. The program may reduce risk of future hypertension development in young adults.

Funding for this research was provided, in part, by a Specialized Center of Research Grant from the National Institutes of Health–National Center for Complementary and Alternative Medicine, and by the Abramson Family Foundation, The David Lynch Foundation, and other private donors. (*Am J Hypertens.* 2009;22(12):1326-1331.) –DC

## OLDER ADULTS WITH ALCOHOL DISORDERS ARE LIKELY TO DRINK MORE WITH AGE

According to previous research, adults generally drink less alcohol as they grow older. A new study, however, not only suggests that the opposite may be true for older adults with alcohol use disorders (AUDs), but that older adults with AUDs may drink even more than younger adults with similar problems.

Using data from the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), Linda Ginzer, MSW, and Virginia E. Richardson, PhD, from Ohio State University, compared the drinking habits of older and younger people, and especially of subjects with AUDs. They analyzed drinking patterns, distinguishing between total alcohol consumption and binge drinking behaviors. Binge drinking was defined as the number of standard sized drinks per day (14 grams of alcohol/drink)—five drinks for men, and four for women.

“Since it is well known that drinking decreases with age overall, we wanted to know if that were true of people with all alcohol use diagnoses, too,” said Ms. Ginzer.

Adults  $>60$  years of age with alcohol dependence were found to consume  $>40$  alcoholic drinks/week on average, compared to  $\sim 30$  drinks per week for those aged 18–30 years with alcohol dependence, and  $\sim 35$  drinks/week for those 40–59 years of age. Adults  $>60$  years of age with alcohol dependence also topped the charts in average frequency of monthly binge drinking with  $>18$  binge episodes/month, compared to 13 binge episodes/month in the cohort 18–21 years of age.

These findings suggest that binge drinking is a better metric than total drinking to gauge problem drinking. Ms. Ginzer also points to separate research showing that older people with AUDs respond just as well to treatment as younger people with similar problems.

“Older people should be referred to treatment instead of being seen as hopeless,” Ms. Ginzer said.

(Results presented at the 62nd Annual Scientific Meeting of the Gerontological Society of America, November 20, 2009, Atlanta, Georgia). –LS

*Psychiatric dispatches is written by Dena Croog and Lonnie Stoltzfoos.*