Cymbalta Approved for GAD

Cymbalta® (duloxetine HCl) has been approved by the U.S. Food and Drug Administration for the treatment of generalized anxiety disorder (GAD).

Its safety and efficacy in GAD was established in three randomized, double-blind, placebo-controlled studies including more than 800 patients with GAD without depression. Results found that core anxiety symptoms significantly improved with Cymbalta (46%), compared with placebo (32%), as measured by the Hamilton Anxiety Scale. Patients taking Cymbalta reported greater improvement in functional impairment associated with GAD, including improved ability to perform everyday activities. Dosages of 60 mg to 120 mg per day were studied; 120 mg per day was effective, but there is no evidence that dosages greater than 60 mg (i.e., the target daily dosage) confer additional benefit.


CMS Declines Full Coverage of VNS Therapy for TRD

The Centers for Medicare and Medicaid Services (CMS) has declined a formal request by Cyberonics, Inc., to reconsider its existing coverage policy for vagus nerve stimulation (VNS) therapy. Cyberonics’ formal request to CMS called for expanded coverage of VNS therapy to include full coverage for patients with treatment-resistant depression (TRD) who have been either previously treated with or refused treatment with electroconvulsive therapy or previously hospitalized for depression.

During the 30-day public comment period, which concluded in March, more than 1,800 positive comments were filed to CMS supporting access to VNS therapy for eligible patients. These comments were submitted by psychiatrists; health care professionals; patients and their families; professional and advocacy organizations, including the American Psychiatric Association, National Alliance on Mental Illness, Depression and Bipolar Support Alliance, and Mental Health America; and approximately 20 members of U.S. Congress.


New Prodrug Approved for ADHD Treatment

The U.S. Food and Drug Administration (FDA) has granted marketing approval for Vyvanse™ (lisdexamfetamine dimesylate, formerly known as NRP-104) for the treatment of attention-deficit/hyperactivity disorder (ADHD). Vyvanse is a prodrug that is therapeutically inactive until metabolized in the body; as such, it has a lower potential for abuse. The FDA has proposed that Vyvanse be classified as a Schedule II controlled substance, which has been accepted by the Drug Enforcement Administration.

Phase 2 and 3 clinical trials demonstrated that 30-mg, 50-mg, and 70-mg dosages of Vyvanse provided significant improvements in ADHD symptoms compared with placebo in children ages 6 to 12, at all time points tested. In a phase 2 analog classroom study, patients’ behavior and academic productivity significantly improved with Vyvanse versus placebo.

In a phase 3 randomized, double-blind, placebo-controlled study, all three dosages of Vyvanse demonstrated significant improvements in ADHD Rating Scale scores, compared with placebo, after 4 weeks of once-daily treatment. In addition, in an open-label phase 3 study, Vyvanse resulted in a 60% improvement in the primary rating scale scores for ADHD symptoms in children ages 6 to 12 who received 6 months of treatment. At 6 months, 95% of children taking Vyvanse produced a “much improved” or “very much improved” rating on the Clinical Global Impressions Improvement score.

ADHD Drug Manufacturers to Notify Patients of Adverse Events

The U.S. Food and Drug Administration (FDA) has directed manufacturers of attention-deficit/hyperactivity disorder (ADHD) drugs to develop Patient Medication Guides to notify patients of possible cardiovascular risks and risks of adverse psychiatric symptoms associated with the drugs and to advise them of precautions they may take. The drugs that are the focus of the revised labeling and new guides include Adderall®, Adderall XR®, Concerta®, Daytrana®, Desoxyn®, Dexedrine®, Focalin®, Focalin XR®, Metadate CD®, Methyltin® (oral solution and chewable tablets), Ritalin®, Ritalin SR®, Ritalin L.A., and Strattera®.

On reviewing reports of serious cardiovascular adverse events in patients taking usual dosages of ADHD drugs, the FDA found incidences of sudden death in patients with underlying serious heart problems or defects and stroke and heart attack in adults with certain risk factors. In addition, another FDA review found a slight increased risk (approximately 1 per 1,000) for drug-related psychiatric adverse events in patients who may not have had previous psychiatric problems.

The FDA recommends that anyone being considered for treatment with ADHD drugs work with a health care professional to develop a treatment plan that includes a careful health history and evaluation of current status, particularly for cardiovascular and psychiatric problems. The draft Patient Medication Guides for each product can be found at http://www.fda.gov/cder/drug/infopage/ADHD/default.htm.


New Program Aids Alcohol Addiction Recovery

The National Institute for Alcohol Recovery (NIFAR) has introduced a new program for recovery from alcohol addiction, called Regenerate. To produce lasting sobriety, Regenerate coaches and empowers drinkers from detoxification to recovery, using advanced multidisciplinary approaches based on the latest scientific and clinical research.

The program targets all aspects of alcohol dependence, including nutritional deficiencies, triggers, relapse, and emotional issues such as anxiety, anger, and relationships. Regenerate is based on repeated neuroadaptation techniques, or “rewiring” the brain, which occur while the individual is brought into a heightened state of emotion.

The program, consisting of a 25-day audio CD, arrives in a confidential package containing a portable case, daily guide, handbook, and four kinds of custom-formulated supplements. It is designed to be a personal companion that provides support and recovery anytime, anywhere.

For more information and to listen to a sample, access NIFAR’s Web site at http://www.nifar.org.


Do You Have Any Product News to Share?

JPN would like to hear about it.

Please forward pertinent information to:

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