

Drugs recently approved or pending approval

LEXAPRO

The US Food and Drug Administration (FDA) has granted approval to Forest Laboratories, Inc. (New York, NY) to market Lexapro (escitalopram oxalate) for the treatment of generalized anxiety disorder (GAD). Lexapro was evaluated in 3 randomized, 8-week, double-blind, placebo-controlled trials and involved approximately 850 patients aged 18 to 80 years who were diagnosed with GAD. The primary efficacy variable in all 3 studies was the Hamilton Anxiety Scale (HAMA) total score. Secondary efficacy measures included changes in HAMA psychic anxiety subscale and Clinical Global Impressions scores. Patients given Lexapro (10 mg to 20 mg) experienced significant improvement in GAD symptoms compared with placebo-treated patients as measured by change in baseline in HAMA score. Sixty-eight percent of Lexapro-treated patients demonstrated a significant improvement in quality of life compared with 41% of placebo-treated patients as measured by the Quality of Life scale. The most common adverse effects reported with Lexapro were nausea, ejaculation disorder, insomnia, fatigue, decreased libido, and anorgasmia. There have been reports of adverse events occurring upon discontinuation of Lexapro, including dysphoric mood, irritability, agitation, dizziness, sensory disturbances, anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. Lexapro should not be taken with monoamine oxidase inhibitors. Lexapro was previously approved for the treatment of major depressive disorder.



RISPERDAL

The FDA has given approval to Janssen Pharmaceutica Products, LP, of Titusville, NJ, to market Risperdal (risperidone) as monotherapy or in combination with lithium or valproate for the short-term treatment of acute manic or mixed episodes associated with bipolar I disorder. The effectiveness of Risperdal was evaluated in 4 studies—2 studies with Risperdal as monotherapy (N = 532) and 2 studies with Risperdal in combination with lithium or valproate (N = 290). In 3 studies (2 monotherapy and 1 combination), patients who received Risperdal experienced significantly greater symptom improvements than those in the control groups. In the fourth study, Risperdal combined with valproate, lithium, or carbamazepine

was not superior to valproate, lithium, or carbamazepine alone. The primary rating instrument used for assessing manic symptoms was the Young Mania Rating Scale (YMRS). The primary outcome was change from baseline in the YMRS total score. Clinical response was defined as a 50% or greater reduction in the total YMRS score from baseline to endpoint. The most common adverse effects associated with Risperdal monotherapy were extrapyramidal symptoms, sleepiness, dyspepsia, nausea, abnormal vision, and increased saliva. The most common adverse effects associated with Risperdal combination therapy were sleepiness, dizziness, parkinsonism, increased saliva, akathisia, abdominal pain, and urinary incontinence. Risperdal should be administered once daily, starting with 2 mg to 3 mg per day. Risperdal was previously approved for the treatment of schizophrenia.

SYMBYAX

Eli Lilly and Company (Indianapolis, IN) was granted approval by the FDA to market Symbyax (olanzapine and fluoxetine HCl) for the treatment of depressive episodes associated with bipolar disorder. Symbyax is the first FDA-approved medication for bipolar depression. The efficacy of Symbyax was evaluated in 2 identically designed, 8-week, randomized, double-blind, controlled studies of patients who met DSM-IV criteria for bipolar I disorder. Patients (N = 788) were randomized to either Symbyax, olanzapine, or placebo. The primary rating instrument used to assess depressive symptoms was the Montgomery-Asberg Depressive Rating Scale (MADRS). The primary outcome measure was the change from baseline to endpoint in the MADRS total score. In both studies, Symbyax was statistically significantly superior to both olanzapine monotherapy and placebo in reduction of MADRS total score. The most common adverse effects reported with Symbyax were asthenia, edema, increased appetite, peripheral edema, pharyngitis, somnolence, abnormal thinking, tremor, and weight gain. Symbyax is contraindicated for use with monoamine oxidase inhibitors and thioridazine. Symbyax should be administered once daily in the evening, generally with the 6 mg/25 mg dosage.

Compiled from press reports and pharmaceutical company press releases. For more information, contact Tricia Carbone, Hospital Physician, 125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.