



Pfizer Receives FDA Approval For Geodon® (Ziprasidone HCl) Capsules For The Adjunctive Maintenance Treatment Of Bipolar Disorder In Adults

Thursday, November 19, 2009 - 09:48pm

Data Show Geodon Used as an Adjunct to Lithium or Valproate Is Effective in the Maintenance Treatment of Bipolar I Disorder

(BUSINESS WIRE)--Pfizer today announced that the U.S. Food and Drug Administration (FDA) has approved Geodon® (ziprasidone HCl) Capsules for maintenance treatment of bipolar I disorder as an adjunct to lithium or valproate in adults. The approval is based on clinical data demonstrating that Geodon is an effective and generally well-tolerated adjunctive treatment for long-term symptom control in patients with bipolar disorder.

Bipolar disorder, which affects approximately 5.7 million adults in the United States, is a debilitating, chronic condition that requires lifelong treatment and management.¹ More than 90 percent of patients with bipolar disorder have recurring mood episodes,² making it important to establish a long-term treatment plan to help prevent recurrence and stabilize mood. The recurrence of mood episodes associated with bipolar disorder can have a devastating impact on patients' lives, and the disease is associated with high rates of disability.³

"The FDA approval of Geodon provides an additional treatment option for patients with bipolar disorder, who require maintenance therapy to keep the symptoms of the disease under control," said Charles Bowden, clinical professor of psychiatry and pharmacology,

University of Texas Health Science Center.

The efficacy and safety of Geodon for the adjunctive maintenance treatment of bipolar disorder were studied in a six-month, double-blind, randomized, placebo-controlled trial in adult patients with bipolar I disorder. After an open-label stabilization period of 10 to 16 weeks, 240 patients were randomized to continue on Geodon plus lithium or valproate, or to have Geodon replaced by placebo.⁴ The primary endpoint in this study was time to recurrence of a mood episode requiring intervention.

The data demonstrated that Geodon plus lithium or valproate was superior to placebo plus lithium or valproate in increasing the time to recurrence of a mood episode. During six months of treatment, 19.7 percent of patients in the Geodon arm required intervention for a mood episode, compared with 32.4 percent of patients in the placebo arm.⁴

The adjunctive Geodon treatment regimen was generally well-tolerated.⁴ Discontinuation due to adverse events occurred in 13 percent of patients in the placebo group, compared with 9 percent of those in the Geodon group.⁵ The safety and tolerability data from this study are consistent with Geodon's already well-established safety profile in adult patients.

"The recurrence of mood episodes associated with bipolar disorder can have a devastating impact on patients' lives," said Dr. Ilise Lombardo, senior medical director, Pfizer Specialty Care. "This approval underscores Pfizer's commitment to supporting people suffering from serious mental health disorders."

Geodon is also FDA-approved for the treatment of acute manic and mixed episodes associated with bipolar disorder, with or without psychotic features, and for the treatment of schizophrenia. Since the FDA approval of Geodon in February 2001, nearly 2 million adult patients have been treated with this important therapy.⁶

Important Safety Information

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death compared to placebo. Geodon is not approved for the treatment of elderly patients with dementia-related psychosis.

Geodon is contraindicated in patients with a known history of QT prolongation, recent acute myocardial infarction, or uncompensated heart failure, and should not be used with other QT-prolonging drugs. Geodon has a greater capacity to prolong the QTc interval

than several antipsychotics. In some drugs, QT prolongation has been associated with torsade de pointes, a potentially fatal arrhythmia. In many cases this would lead to the conclusion that other drugs should be tried first.

As with all antipsychotic medications, a rare and potentially fatal condition known as neuroleptic malignant syndrome (NMS) has been reported with Geodon. NMS can cause hyperreflexia, muscle rigidity, diaphoresis, tachycardia, irregular pulse or blood pressure, cardiac dysrhythmia, and altered mental status. If signs and symptoms appear, immediate discontinuation, treatment, and monitoring are recommended.

Prescribing should be consistent with the need to minimize tardive dyskinesia (TD), a potentially irreversible dose- and duration-dependent syndrome. If signs and symptoms appear, discontinuation should be considered since TD may remit partially or completely.

Hyperglycemia-related adverse events, sometimes serious, have been reported in patients treated with atypical antipsychotics. There have been few reports of hyperglycemia or diabetes in patients treated with Geodon, and it is not known if Geodon is associated with these events. Patients treated with an atypical antipsychotic should be monitored for symptoms of hyperglycemia.

Precautions include the risk of rash, orthostatic hypotension, and seizures.

In short-term schizophrenia trials, the most commonly observed adverse events associated with Geodon at an incidence of $\geq 5\%$ and at least twice the rate of placebo were somnolence and respiratory tract infection.

The most common adverse events associated with Geodon in adult patients with bipolar mania were somnolence, extrapyramidal symptoms, dizziness, akathisia, and abnormal vision.

Please visit www.GEODON.com for full prescribing and patient information.

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1 National Institute of Mental Health. Bipolar disorder. Available at: <http://www.nimh.nih.gov/health/publications/bipolar-disorder/nimhbipolar.pdf>. Accessed October 27, 2009.

2 Solomon DA, Keitner GI, Miller IW, Shea MT, Keller MB. Course of illness and maintenance treatments for patients with bipolar disorder. *J Clin Psychiatry*. 1995;56:5-13.

3 Sajatovic M. Bipolar disorder: disease burden. *Am J Manag Care*. 2005;11:S80-S84.

4 Vieta E, Bowden C, Ice KS, et al. A 6-month, randomized, placebo-controlled, double-blind trial of ziprasidone plus a mood stabilizer in subjects with bipolar I disorder. Poster presented at the 17th European Psychiatric Association European Congress of Psychiatry, January 25, 2009, Lisbon, Portugal.

5 Pfizer Inc. Clinical study report synopsis: Protocol A1281137. A phase 3, randomized, 6-month, double blind trial in subjects with bipolar I disorder to evaluate the continued safety and maintenance of effect of ziprasidone plus a mood stabilizer (vs placebo plus a mood stabilizer) following a minimum of 2 months of response to open-label treatment with both agents.

6 Data on file. Pfizer Inc.

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