FDA Issues Complete Response Letter for RISPERDAL(R) CONSTA(R) for Adjunctive Maintenance Treatment of Bipolar Disorder

February 10, 2009

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 10, 2009-- Alkermes, Inc. (NASDAQ: ALKS) today announced that the Food and Drug Administration (FDA) has asked Alkermes' partner, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD), for additional information regarding the supplemental New Drug Application (sNDA) for RISPERDAL® CONSTA® ((risperidone) Long-Acting Injection). The sNDA, submitted in April 2008, sought approval for RISPERDAL CONSTA for adjunctive maintenance treatment to delay the occurrence of mood episodes in patients with bipolar disorder who relapsed frequently.

The Agency's complete response outlined questions that need to be addressed prior to granting approval for the new indication, but did not request additional studies.

J&JPRD is currently evaluating the FDA's complete response letter and will work with the Agency to resolve any outstanding questions.

Bipolar disorder is a brain disorder that causes unusual shifts in a person's mood, energy and ability to function. It is often characterized by debilitating mood swings from extreme highs (mania) to extreme lows (depression), and affects 5.7 million, or 2.6 percent, of the American adult population in any given year.[1]

RISPERDAL CONSTA is marketed in the U.S. by Janssen®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and manufactured by Alkermes, Inc. RISPERDAL CONSTA was initially approved for the treatment of schizophrenia in the U.S. in 2003 and is registered in more than 80 countries worldwide. Using Alkermes' proprietary Medisorb ® drug-delivery technology, the RISPERDAL CONSTA formulation encapsulates risperidone in microspheres made of a biodegradable polymer, which are suspended in a water-based solution and injected into the muscle. Laboratory and clinical research has shown that the microspheres gradually degrade at a set rate to provide therapeutic blood levels of the drug in the bloodstream for an extended period. The polymer from which the microspheres are made breaks down into two naturally occurring compounds that are then eliminated by the body.

RISPERDAL CONSTA is used for the treatment of schizophrenia.

IMPORTANT SAFETY INFORMATION FOR RISPERDAL® CONSTA®

Elderly Patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. RISPERDAL® CONSTA® ((risperidone) Long-Acting Injection) is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS) is a rare and potentially fatal side effect reported with RISPERDAL® CONSTA® and similar medicines. Call your doctor immediately if the person being treated develops symptoms such as high fever; stiff muscles; shaking; confusion; sweating; changes in pulse, heart rate, or blood pressure; or muscle pain and weakness. Treatment should be stopped if the person being treated has NMS.

Tardive Dyskinesia (TD) is a serious, sometimes permanent side effect reported with RISPERDAL® CONSTA® and similar medications. TD includes uncontrollable movements of the face, tongue, and other parts of the body. The risk of developing TD and the chance that it will become permanent is thought to increase with the length of therapy and the overall dose taken by the patient. This condition can develop after a brief period of therapy at low doses, although this is much less common. There is no known treatment for TD, but it may go away partially or completely if therapy is stopped.

High blood sugar and diabetes have been reported with RISPERDAL® CONSTA® and similar medications. If the person being treated has diabetes or risk factors such as being overweight or a family history of diabetes, blood sugar testing should be performed at the beginning and throughout treatment with RISPERDAL® CONSTA®. Complications of diabetes can be serious and even life threatening. If signs of high blood sugar or diabetes develop, such as being thirsty all the time, going to the bathroom a lot, or feeling weak or hungry, contact your doctor.

RISPERDAL® CONSTA® and similar medications can raise the blood levels of a hormone known as prolactin, causing a condition known as hyperprolactinemia. Blood levels of prolactin remain elevated with continued use. Some side effects seen with these medications include the absence of a menstrual period; breasts producing milk; the development of breasts by males; and the inability to achieve an erection. The connection between prolactin levels and side effects is unknown.

Some people taking RISPERDAL® CONSTA® may feel faint or lightheaded when they stand up or sit up too quickly. By standing up or sitting up slowly and following your healthcare professional's dosing instructions, this side effect can be reduced or it may go away over time.

RISPERDAL® CONSTA® may affect your alertness or driving ability; therefore, do not drive or operate machinery before talking to your healthcare professional.

RISPERDAL® CONSTA® should be used cautiously in people with a seizure disorder, who have had seizures in the past, or who have conditions that increase their risk for seizures.

Extrapyramidal Symptoms (EPS) are usually persistent movement disorders or muscle disturbances, such as restlessness, tremors, and muscle stiffness. If you observe any of these symptoms, talk to your healthcare professional.

Inform your healthcare professional if you become pregnant or intend to become pregnant during therapy with RISPERDAL® CONSTA®. Caution should be exercised when RISPERDAL® CONSTA® is administered to a nursing woman.

RISPERDAL® CONSTA® may make you more sensitive to heat. You may have trouble cooling off, or be more likely to become dehydrated, so take care when exercising or when doing things that make you warm.

Some medications interact with RISPERDAL® CONSTA®. Please inform your healthcare professional of any medications or supplements that you are taking. Avoid alcohol while on RISPERDAL® CONSTA®.

In a study of people taking RISPERDAL® CONSTA®, the most common side effects in the treatment of schizophrenia were headache, tremors, dizziness, restlessness, tiredness, constipation, indigestion, sleepiness, weight gain, pain in the limbs, and dry mouth.

If you have any questions about RISPERDAL® CONSTA® or your therapy, talk with your doctor.

About Alkermes

Alkermes, Inc. is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. Alkermes developed, manufactures and commercializes VIVITROL® for alcohol dependence and manufactures RISPERDAL® CONSTA® for schizophrenia. Alkermes' robust pipeline includes extended-release injectable, pulmonary and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Cambridge, Massachusetts, Alkermes has research facilities in Massachusetts and a commercial manufacturing facility in Ohio.

Certain statements set forth above may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and the company's business is subject to significant risk and uncertainties and there can be no assurance that its actual results will not differ materially from its expectations. These risks and uncertainties include, among others, the ability of Alkermes' partner to respond to the FDA complete response and the ultimate decisions by the FDA relating to the sNDA for RISPERDAL CONSTA for adjunctive maintenance treatment in patients with bipolar disorder. For further information with respect to factors that could cause the company's actual results to differ materially from expectations, reference is made to the reports the Company filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended. The forward-looking statements made in this release are made only as of the date hereof and the company disclaims any intention or responsibility for updating predictions or financial expectations contained in this release.

[1] Kessler RC, Chiu WT, Demler O, Walters EE. Prevalence, severity, and comorbidity of twelve-month DSM-IV disorders in the National Comorbidity Survey Replication (NCS-R). *Archives of General Psychiatry*, 2005 Jun;62(6):617-27.

Source: Alkermes

Alkermes, Inc.
Rebecca Peterson, 617-583-6378
Corporate Communications