Supplemental New Drug Application for RISPERDAL(R) CONSTA(R) Submitted to the FDA for the Treatment of Bipolar Disorder

July 24, 2008

CAMBRIDGE, Mass.--(BUSINESS WIRE)--July 24, 2008--Alkermes, Inc. (NASDAQ: ALKS) today announced that its partner, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD), submitted a supplemental New Drug Application (sNDA) for RISPERDAL(R) CONSTA(R) ((risperidone) Long-Acting Injection) to the U.S. Food and Drug Administration (FDA) for approval as monotherapy in the maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes in adults.

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

"RISPERDAL CONSTA, currently an important therapy for the treatment of schizophrenia, is the first and only long-acting, atypical antipsychotic commercially available," stated Dr. Elliot Ehrich, chief medical officer of Alkermes. "The approval of RISPERDAL CONSTA for the maintenance treatment of bipolar I disorder would bring patients and their physicians a novel and valuable treatment option for managing this serious, chronic disease."

In April 2008, J&JPRD submitted another sNDA for RISPERDAL CONSTA to the FDA seeking approval for adjunctive maintenance treatment to delay the occurrence of mood episodes in patients with frequently relapsing bipolar disorder (FRBD). FRBD, defined as four or more manic or depressive episodes in the previous year that require a doctor's care, may affect 10 to 20 percent of people with bipolar disorder.(2)

RISPERDAL CONSTA was approved for the treatment of schizophrenia in the U.S. in 2003 and is now approved in more than 80 countries worldwide. RISPERDAL CONSTA is marketed by Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., in the U.S. and is manufactured by Alkermes.

RISPERDAL CONSTA uses Alkermes' proprietary Medisorb(R) technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. Available in 12.5 mg, 25 mg, 37.5 mg and 50 mg dose units, RISPERDAL CONSTA is approved for the treatment of schizophrenia. For more information about RISPERDAL CONSTA, visit http://www.risperdalconsta.com.

About Bipolar Disorder

It is estimated that 5.7 million adults in the U.S. and 27 million people worldwide suffer from bipolar disorder, also known as manic-depressive disorder. It is characterized by debilitating mood swings, from extreme highs (mania) to extreme lows (depression). Signs of mania include euphoria, extreme irritability or rage, accelerated or disorganized thinking and an increase in risky behaviors. Signs of depression include intense sadness or despair, loss of energy, insomnia and suicidal thoughts.(1,3)

Approximately 10 to 20 percent of patients with bipolar disorder seen in mood disorder clinics are identified as "rapid-cycling" and have had four or more episodes during the previous 12 months. The types of mood episodes (manic, depressed, mixed) seen in these patients can occur in any pattern. The course of their illness is characterized by poorer outcomes as well as requirements for more concomitant medications and more healthcare resources.

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) is not approved for the treatment of patients with dementia-related psychosis.

In a study of people taking RISPERDAL CONSTA, the most common side effects in the treatment of schizophrenia were sleepiness, restlessness, tremors and muscle stiffness, stomach upset, constipation, dry mouth, feeling tired and weight increase.

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.

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.

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.

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.

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.

Inform your healthcare professional if you become pregnant or intend to become pregnant during therapy with RISPERDAL CONSTA. Also, tell your healthcare professional if you are planning to breast-feed.

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

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.

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

About Alkermes

Alkermes, Inc., a biotechnology company committed to developing innovative medicines to improve patients' lives, manufactures RISPERDAL(R) CONSTA(R) for schizophrenia and developed and manufactures VIVITROL(R) for alcohol dependence. 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 and manufacturing facilities in Massachusetts and Ohio. For more information about Alkermes, visit http://www.alkermes.com.

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, decisions by the FDA relating to the recently submitted sNDAs for RISPERDAL CONSTA for the treatment of bipolar disorder and FRBD. 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.

(2) DSM-IV-TR, American Psychiatric Association, 2000.

(3) The Global Burden of Disease. World Health Organization, 2003. Available at http://www.who.int/mip/2003/other_documents/en/globalburdenofdisease.pdf, accessed July 21, 2008. (Due to its length, this URL may need to be copied/pasted into your Internet browser's address field. Remove the extra space if one exists.)

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