Alkermes Announces Initiation of First Clinical Study for a Four-Week Long-Acting Injectable Formulation of Risperidone

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 9, 2009--Alkermes, Inc. (NASDAQ: ALKS) today announced that its partner, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD), has initiated a phase 1 study of a four-week long-acting injectable formulation of risperidone for the treatment of schizophrenia. The single-dose, open-label study is designed to assess the pharmacokinetics, safety and tolerability of a gluteal injection of this risperidone formulation in approximately 26 patients diagnosed with chronic, stable schizophrenia. A two-week long-acting injectable formulation of risperidone, marketed as RISPERDAL(R) CONSTA(R) ((risperidone) Long-Acting Injection), is commercially available in more than 60 countries.

"We are pleased to build upon our formulation expertise with RISPERDAL CONSTA , an important therapy with demonstrated ability to improve outcomes for many patients with schizophrenia," stated Dr. Elliot Ehrich, chief medical officer of Alkermes. "Patients and physicians need multiple, effective options to treat schizophrenia, including different types of dosing regimens. A four-week long-acting injectable formulation of risperidone would provide another valuable approach for managing this serious, chronic disease."

RISPERDAL CONSTA is manufactured by Alkermes and marketed in the U.S. by Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. Administered once every two weeks, RISPERDAL CONSTA is the first and only long-acting atypical antipsychotic commercially available in the U.S. The extended-release formulation is based on Alkermes' proprietary Medisorb(R) technology, which enables the controlled, extended-release of medication into the body over time and alleviates the need for daily dosing.

About Schizophrenia

Schizophrenia is a chronic, severe and disabling brain disorder. The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions, and social withdrawal), as well as by disorganized thinking. An estimated 2.4 million Americans have schizophrenia, with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia, one of the most serious types of mental illness.

About RISPERDAL CONSTA

RISPERDAL CONSTA was approved for the treatment of schizophrenia in the U.S. in 2003 and is commercially available in more than 60 countries. The medication uses Alkermes' proprietary Medisorb 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. RISPERDAL CONSTA is marketed by Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., in the U.S. and is manufactured by Alkermes. For more information about RISPERDAL CONSTA, visit http://www.risperdalconsta.com.

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. is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. Alkermes developed, manufactures and commercializes VIVITROL(R) for alcohol dependence and manufactures RISPERDAL(R) CONSTA(R) 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, including, but not limited to the development activities for a four-week long-acting injectable formulation of risperidone and the therapeutic potential of this four-week formulation in schizophrenia. 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: whether the clinical trial discussed in this release will be completed on time or at all; potential changes in cost, scope and duration of the clinical trial; and whether a four-week long-acting injectable formulation of risperidone will be approved by regulatory authorities. 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.

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