

## RISPERDAL(R) CONSTA(R) Approved in Japan

April 27, 2009

## -- First Atypical Antipsychotic to be Available as a Long-Acting Injection --

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 27, 2009-- Alkermes, Inc. (NASDAQ: ALKS) today announced that Janssen Pharmaceutica K.K. received approval from the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan to market RISPERDAL® CONSTA® [(risperidone) long-acting injection] for the treatment of schizophrenia. RISPERDAL CONSTA is the first long-acting atypical antipsychotic to be available in Japan. Janssen Pharmaceutica K.K. expects to launch the product in Japan promptly after its listing on Japan's National Health Insurance (NHI) Drug Price Standard.

"The approval of RISPERDAL CONSTA in Japan represents another important market opportunity for the product," commented David Broecker, chief executive officer of Alkermes. "As the first and only long-acting atypical antipsychotic approved for use in Japan, RISPERDAL CONSTA could provide a valuable new treatment option for patients managing this serious, chronic disease."

Under the development and supply agreement between Janssen-Cilag and Alkermes for RISPERDAL CONSTA, Janssen-Cilag is responsible for worldwide sales and marketing of the product. Alkermes is responsible for worldwide manufacturing and receives manufacturing fees and royalties on product sales. RISPERDAL CONSTA was initially approved for the treatment of schizophrenia by the U.S. Food and Drug Administration in 2003 and is registered in more than 80 countries worldwide.

RISPERDAL CONSTA is a long-acting injectable form of risperidone that was developed utilizing Alkermes' proprietary Medisorb <sup>®</sup> drug-delivery technology. Using this technology, risperidone is encapsulated in microspheres made of a biodegradable polymer, which are suspended in a water-based solution and administered to patients by intramuscular injection once every two weeks. 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. For more information about RISPERDAL CONSTA, visit <a href="http://www.risperdalconsta.com">http://www.risperdalconsta.com</a>.

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. Worldwide, it is estimated that one person in every 100 develops schizophrenia, one of the most serious types of mental illness.

## 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 headache, tremors, dizziness, restlessness, tiredness, constipation, indigestion, sleepiness, weight gain, pain in the limbs, and dry mouth.

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. 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.

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<sup>®</sup> for alcohol dependence and manufactures RISPERDAL<sup>®</sup> CONSTA<sup>®</sup> 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, whether RISPERDAL CONSTA will be launched and commercialized successfully in Japan by Janssen Pharmaceutica K.K. 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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Source: Alkermes, Inc.

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