FDA Approves New Injection Site for RISPERDAL(R) CONSTA(R) for Schizophrenia Treatment

October 9, 2008

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Alkermes, Inc. (NASDAQ: ALKS) today announced that patients with schizophrenia now have a new administration option for RISPERDAL(R) CONSTA(R) ((risperidone) Long-Acting Injection). The U.S. Food and Drug Administration (FDA) has approved a new injection site, the deltoid muscle in the arm, for RISPERDAL CONSTA for the treatment of patients with schizophrenia. RISPERDAL CONSTA was previously approved as a gluteal injection only.

"RISPERDAL CONSTA serves an important role in the treatment of schizophrenia by providing consistent levels of medication over a two-week period," stated John Kane, M.D., Chairman of Psychiatry at The Zucker Hillside Hospital. "The ability to inject RISPERDAL CONSTA in the upper arm may be easier for some patients and physicians and also gives patients a choice of where to receive their long-acting therapy."

The application was based on a study showing that the deltoid and gluteal injections of RISPERDAL CONSTA were bioequivalent(1) routes of administration and thus interchangeable. An additional study was conducted that showed the safety and tolerability of RISPERDAL CONSTA injected into the deltoid muscle were similar to the gluteal injections. Both studies were recently presented at the 161st Annual Meeting of the American Psychiatric Association (APA) in Washington, D.C., 2008(2,3).

The new RISPERDAL CONSTA dose packs will now include two separate (non-interchangeable) needles for injection and will be available to U.S. physicians by the end of 2008. The needle for deltoid injection is a smaller gauge and is shorter in length than the gluteal needle. Both are administered every two weeks. Not all patients will be appropriate for the deltoid injection site. As with all medications, it's important that patients discuss their treatment options with their healthcare professional.

RISPERDAL CONSTA is marketed in the U.S. by Janssen(R), Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and manufactured by Alkermes. 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(R) 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.

Worldwide, it is estimated that one person in every 100 develops schizophrenia(4), one of the most serious types of mental illness. An estimated 2.4 million Americans have schizophrenia, with men and women affected equally(5). The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions, and social withdrawal), as well by disorganized thinking, speech and behavior.

RISPERDAL CONSTA ((risperidone) Long-Acting Injection) 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) 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, indigestions, 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., 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, the date of availability of the new RISPERDAL CONSTA dose packs to U.S. physicians and the degree to which study results of the deltoid injection will be predictive of results in commercial use. 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) The FDA has defined bioequivalence as, "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." (FDA, 2003).

(2) Ning X, Thyssen A, Quiroz J et al., Tolerability and safety of long-acting injectable risperidone in chronic schizophrenia subjects using deltoid muscle as an alternative injection site, presented at the 161st Annual Meeting of the American Psychiatric Association (APA) in Washington, D.C.

(3) Thyssen A, Ning X, Herben V et al., Pharmacokinetics of long-acting injectable risperidone injected in deltoid muscle compared to gluteal muscle injection in subjects with schizophrenia, presented at the 161st Annual Meeting of the American Psychiatric Association (APA) in Washington, D.C.

(4) Royal College of Psychiatrists website: http://www.rcpsych.ac.uk/default.aspx?page=1643. Accessed April 14, 2008.

(5) American Psychiatric Association. Let's talk facts about schizophrenia. Available at: http://healthyminds.org/factsheets/LTF-Schizophrenia.pdf. Accessed April 1, 2008.

Source: Alkermes, Inc.