FDA Approves New Dose of RISPERDAL(R) CONSTA(R) for Schizophrenia Treatment

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TITUSVILLE, N.J., and CAMBRIDGE, Mass., April 13 /PRNewswire-FirstCall/ -- The U.S. Food and Drug Administration (FDA) approved a 12.5 mg dose of RISPERDAL® CONSTA® [(risperidone) Long-Acting Injection] for the treatment of schizophrenia within specific patient populations, including those with renal and hepatic impairment. The new dose of RISPERDAL CONSTA will provide physicians with more options to individualize treatment approaches and adjust therapies when clinical factors warrant dose changes. RISPERDAL CONSTA is manufactured by Alkermes, Inc. (Nasdaq: ALKS) and marketed in the U.S. by Janssen, L.P.

"The 12.5 mg dose of RISPERDAL CONSTA will help clinicians to customize treatment for each patient, particularly those who have hepatic or renal impairment and need lower doses," said Henry Nasrallah, M.D., Professor of Psychiatry and Neuroscience, and Director of the Schizophrenia Research Program at the University of Cincinnati. "In addition, this smaller dose will be relevant for patients who may be at risk for drug-drug interactions which could increase the plasma concentrations of RISPERDAL CONSTA, or in patients who have a history of low tolerability to the usual starting doses of psychotropic medications."

The new dose of RISPERDAL CONSTA, which is expected to be available by May 1, is the lowest formulation of the long-acting injection. RISPERDAL CONSTA is also available in 25 mg, 37.5 mg and 50 mg dose units. The FDA approval of the 12.5 mg dose was based on pharmacokinetic data in schizophrenia patients that demonstrated an expected profile for the lower dosage strength. The efficacy of the 12.5 mg dose has not been investigated in clinical trials.

RISPERDAL CONSTA was approved for the treatment of schizophrenia in the U.S. in 2003.

Using proprietary Medisorb® drug-delivery technology developed by Alkermes, 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.

For more information, refer to the full U.S. prescribing information at http://www.risperdalconsta.com/

Janssen, L.P., based in Titusville, N.J., is the only large pharmaceutical company in the U.S. dedicated solely to mental health. The company currently markets prescription medications for the treatment of schizophrenia, bipolar mania and the treatment of symptoms associated with autistic disorder. For more information about Janssen, L.P. visit http://www.janssen.com.

Alkermes, Inc. is a biotechnology company that develops innovative medicines designed to yield better therapeutic outcomes and improve the lives of patients with serious disease. Alkermes currently has two commercial products: RISPERDAL® CONSTA® [(risperidone) long-acting injection], the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, and marketed worldwide by Janssen-Cilag (Janssen), a wholly owned division of Johnson & Johnson; and VIVITROL® (naltrexone for extended- release injectable suspension) the first and only once-monthly injectable medication approved for the treatment of alcohol dependence and marketed in the U.S. primarily by Cephalon, Inc. Alkermes' 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. Alkermes' headquarters are in Cambridge, Massachusetts, and it operates research and manufacturing facilities in Massachusetts and Ohio. For more information, visit http://www.alkermes.com.

Worldwide, it is estimated that one person in every 100 develops schizophrenia, one of the most serious types of mental illness. In the U.S., there are currently 2 million people with schizophrenia, with men and women affected equally. The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions, and social withdrawal), as well by disorganized thinking.

RISPERDAL CONSTA (risperidone) Long-Acting Injection is the first and only long-acting, atypical antipsychotic to be approved by the U.S. Food and Drug Administration and now is approved in more than 70 countries worldwide. The treatment uses Alkermes proprietary Medisorb® technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. RISPERDAL CONSTA Long-Acting injection is manufactured by Alkermes, Inc. (Nasdaq: ALKS) and marketed in the United States by Janssen, L.P. Available in 12.5 mg, 25 mg, 37.5 mg and 50 mg dose units, it is approved for the treatment of schizophrenia. For more information about Janssen, L.P., visit http://www.janssen.com.

IMPORTANT SAFETY INFORMATION

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, 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. There is no known connection between prolactin levels and side effects.

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.

SOURCE Janssen, L.P.; Alkermes, Inc. (JNJ ALKS)

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