



## **Alkermes Announces Submission of New Drug Application for RISPERDAL(R) CONSTA(R) in Japan**

December 20, 2006

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 20, 2006--Alkermes, Inc. (Nasdaq: ALKS) today announced that the Japanese organization of its partner Janssen-Cilag, Janssen Pharmaceutica K.K., submitted a new drug application to the Pharmaceuticals and Medical Devices Agency (PMDA) for marketing approval in Japan of RISPERDAL(R) CONSTA(R) ((risperidone) long-acting injection), an atypical antipsychotic medication for the treatment of schizophrenia. RISPERDAL CONSTA is the first and only long-acting, atypical antipsychotic approved by the U.S. Food and Drug Administration and now is approved in more than 70 countries worldwide.

RISPERDAL CONSTA is a long-acting injectable form of risperidone that uses Alkermes' proprietary Medisorb(R) technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. RISPERDAL CONSTA is administered for the management of schizophrenia -- a brain disorder affecting 1-2% of the world's population.

Under the development and supply agreement between Janssen-Cilag and Alkermes, RISPERDAL CONSTA is manufactured by Alkermes, and Janssen-Cilag is responsible for worldwide sales and marketing of the product. Alkermes receives manufacturing fees and royalties on product sales of RISPERDAL CONSTA.

**Important safety information: Increased Mortality in Elderly Patients with Dementia-Related Psychosis:**

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. RISPERDAL CONSTA 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 were: sleepiness, restlessness, tremors and muscle stiffness, stomach upset, constipation, dry mouth, feeling tired and weight increase. Studies suggest an increased risk of elevated blood sugar-related side effects, which are sometimes potentially fatal, in patients treated with this class of medications, including RISPERDAL CONSTA. Some people may need regular blood sugar testing.

Patients may have heard the term "tardive dyskinesia." These are potentially persistent, uncontrollable, slow or jerky facial or body movements that can be caused by all medications of this type. If patients have these symptoms, they should talk with their health care professional.

A rare but serious side effect that has been reported with this kind of medicine, including RISPERDAL CONSTA, is known as NMS or neuroleptic malignant syndrome. NMS is characterized by muscle rigidity and fever and can be serious.

For more information, refer to the full prescribing information at <http://www.janssen.com>.

About Alkermes, Inc.

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(R) CONSTA(R) ((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(R) (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.

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 Japanese Regulatory Authorities relating to the recently submitted NDA for RISPERDAL CONSTA for the treatment of schizophrenia. 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.

Medisorb(R) is a trademark of Alkermes, Inc., VIVITROL(R) is a trademark of Cephalon, Inc. and RISPERDAL(R) CONSTA(R) is a registered trademark of Johnson & Johnson Corporation.

CONTACT:

Alkermes, Inc.

Rebecca Peterson, 617-583-6378

Corporate Communications

SOURCE:  
Alkermes, Inc.