Alkermes Submits Marketing Authorization Application for Vivitrol(R) in the United Kingdom and Germany

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CAMBRIDGE, Mass., Apr 02, 2007 (BUSINESS WIRE) -- Alkermes, Inc. (Nasdaq: ALKS) today announced that the company has submitted a Marketing Authorization Application (MAA) for VIVITROL® (naltrexone for extended-release injectable suspension) to regulatory authorities in the United Kingdom (Medicines and Healthcare Products Regulatory Agency, or MHRA) and Germany (Bundesinstitut fur Arzneimittel und Medizinprodukte, or BfArM). VIVITROL, the first and only once-monthly treatment for alcohol dependence, was approved by the U.S. Food and Drug Administration (FDA) in April 2006.

The MAA for VIVITROL was submitted under a decentralized procedure, in which the United Kingdom will act as the Reference Member State and Germany will act as the Concerned Member State for the application. If successful, a filing under the decentralized procedure would result in a simultaneous approval of VIVITROL as a treatment for alcohol dependence in these two countries.

"This MAA submission is a key milestone for Alkermes and reflects our targeted approach to commercialize VIVITROL in Europe on a country by country basis," stated David Broecker, President and Chief Executive Officer at Alkermes. "Alcohol dependence, which affects approximately 23 million individuals in Europe, is a serious disease affecting the brain and warrants medication as part of treatment. The strong clinical profile and unique, once-monthly administration of VIVITROL could provide a valuable new treatment option for alcohol dependent patients and their treatment providers."

The MAA for VIVITROL is based on the safety and efficacy data from a six-month, multi-center, double-blind, randomized, placebo-controlled phase 3 study in 624 alcohol dependent patients, more than 90% of whom were actively drinking at study enrollment. The primary endpoint of the study was the reduction in the event rate of heavy drinking days. Heavy drinking is defined as five or more drinks per day for men and four or more drinks per day for women. The MAA for VIVITROL also includes reference to oral naltrexone (marketed as NALOREX® in the United Kingdom and NEMEXIN® in Germany) and its approval in a number of EU Member States, including Austria, Denmark, France, Italy and Sweden, as a treatment for alcohol dependence.

For full U.S. VIVITROL prescribing information, including its boxed warning, please call 1-800-VIVITROL (1-800-848-4876) or visit www.vivitrol.com.

About VIVITROL

VIVITROL is the first and only once-monthly, extended-release injectable medication for the treatment of alcohol dependence and was approved by the U.S. FDA in April 2006. VIVITROL is administered by a healthcare provider and should be used in combination with psychosocial support. The proprietary Medisorb® drug delivery technology in VIVITROL enables the medication to be gradually released into the body at a controlled rate over a one-month time period.

About Alcohol Dependence

Alcohol dependence is a serious and chronic disease that affects multiple regions of the brain, providing rationale for the use of medication with psychosocial support as part of an integrated treatment plan. Underlying neurological and genetic factors, as well as environmental factors, play a role in alcohol dependence;(1) therefore, there is a need for a variety of treatment options that can be tailored to best suit patients' needs. Psychosocial support, such as counseling or group therapy, is the traditional approach for treating alcohol dependence; however, experts in the field increasingly recommend and support a treatment approach that includes a combination of medication and psychosocial support.(2),(3)

Of the 486 million people in the European Union,(4) there are approximately 23 million individuals who are dependent on alcohol.(5) Alcohol is causally related to more than 60 medical conditions, including heart disease, liver disease, infectious disease, and cancer,(6),(7) and contributes to nearly one in ten of all ill-health and premature deaths in Europe each year.(8) In Europe, alcohol is the third most important risk factor, after smoking and high blood pressure, for ill-health and premature death.(8) Alcohol abuse and dependency are an economic burden to society that cost Europeans nearly EUR 400 billion in tangible and intangible costs annually.(9)

About Alkermes

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.

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 potential marketing approval of VIVITROL in the United Kingdom and Germany. 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 whether MHRA and BfArM accept the MAA submission for VIVITROL and whether VIVITROL receives marketing approval in the United Kingdom and Germany. For further information with respect to factors that could cause the company's actual results to differ 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 guidance contained in this release.

(1) Nestler, EJ and Malenka, RC. The Addicted Brain. Scientific American, 2004:78-85.

(2) Saitz R. Unhealthy Alcohol Use. New England Journal of Medicine, 2005; 352:596-607.

(3) U.S. Department of Health and Human Services, National Institutes of Health, Helping Patients Who Drink too Much: A Clinician's Guide, 2005.

(4) The World Factbook. Retrieved March 2007 from https://www.cia.gov/cia/publications/factbook/print/ee.html.

(5) Alcohol In Europe, A Public Health Perspective, Institute of Alcohol Studies, UK June 2006, Chapter 4, pg 75.

(6) Room R, Babor T, Rehm J. Alcohol and public health. Lancet, 2005; 365:519-530.

(7) Bagnardi V; Blangiardo M; Vecchia C, et al. Alcohol consumption and the risk of cancer. Alcohol Res Health. 2001; 25(4):263-270.

(8) Kaplan, W. Alcohol Use Disorders: Alcoholic Liver Diseases and Alcohol Dependency Opportunities to Address Pharmaceutical Gaps. In Priority Medicines for Europe and the World: A Public Health Approach to Innovation, 2004, Chapter 6.14, pg 10.

(9) Alcohol In Europe, A Public Health Perspective, Institute of Alcohol Studies, UK June 2006, Chapter 3, pg 65.

SOURCE: Alkermes, Inc.

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