



## **Alkermes Announces Priority Review Granted for Vivitrex -Naltrexone Long-Acting Injection- NDA Submission**

May 27, 2005

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 27, 2005--Alkermes, Inc. (Nasdaq: ALKS) today announced that the New Drug Application ("NDA") for Vivitrex(R) (naltrexone long-acting injection) has been accepted for review by the United States Food and Drug Administration ("FDA") and has been granted a Priority Review designation. The Prescription Drug User Fee Act ("PDUFA") date for completion of review by the FDA of the Vivitrex NDA is September 30, 2005. Vivitrex is being developed as the first long-acting medication available for the treatment of alcohol dependence (in conjunction with counseling) that is administered once-monthly, or every four weeks, by injection.

"We believe that the acceptance of our Vivitrex NDA for review is another key step in our ongoing commitment to bring this important medicine to alcohol dependent patients," stated Richard Pops, chief executive officer of Alkermes. "The Agency's decision to grant the application Priority Review status underscores the importance of our goal to make a new treatment option available to patients for this chronic and devastating disease."

Vivitrex, an injectable, long-acting formulation of the currently approved drug naltrexone, was designed utilizing Alkermes' proprietary Medisorb(R) drug-delivery technology. Using the Medisorb technology, naltrexone is encapsulated in microspheres made of a biodegradable polymer that dissolves slowly and release drug at a controlled rate following intramuscular injection.

### About Alcohol Dependence

In the U.S., approximately 18 million people are dependent on or abuse alcohol(1) and 2.3 million adults seek treatment each year(2). Taking prescribed medication, an important determinant in therapeutic outcomes(3), is particularly challenging for patients with addictive disorders such as alcohol dependence(4). Alcohol is causally related to more than 60 medical conditions, including heart disease, liver disease, infectious disease, and cancer(5,6) and contributes to more than 100,000 deaths in the U.S. each year(7). In addition, alcohol dependence accounts for approximately \$134 billion in lost earnings annually(8).

### About Alkermes, Inc.

Alkermes, Inc. is a pharmaceutical company that develops products based on sophisticated drug delivery technologies to enhance therapeutic outcomes in major diseases. The Company's lead commercial product, Risperdal Consta(R) ((risperidone) long-acting injection), is the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, and is marketed worldwide by Janssen-Cilag ("Janssen"), a wholly owned subsidiary of Johnson & Johnson. The Company's lead proprietary product candidate, Vivitrex(R) (naltrexone long-acting injection), is being developed as a once-monthly injection for the treatment of alcohol dependence. The Company has a pipeline of extended-release injectable products and pulmonary drug products based on its proprietary technology and expertise. Alkermes' product development strategy is twofold: the Company partners its proprietary technology systems and drug delivery expertise with several of the world's finest pharmaceutical companies and it also develops novel, proprietary drug candidates for its own account. The Company's 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. 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.

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(2) Alkermes Forecasting Data 2005.

(3) Weiss RD. Adherence to pharmacotherapy in patients with alcohol and opioid dependence. *Addiction* 2004; 99: 1382-1392.

(4) Rinn W, Desai N, Rosenblatt H, Gastfriend DR. Addiction denial and cognitive dysfunction: A preliminary investigation. *J Neuropsychiatry Clin Neurosci* 2002; 14: 52-57.

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

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

(7) McGinnis JM, Foege WH. Mortality and morbidity attributable to use of addictive substances in the United States. *Proc Assoc. Am. Physicians*. 1999; 111:109-118.

(8) US DHHS: The Economic Costs of Alcohol and Drug Abuse in the United States: Estimates, Update Methods, and Data, 2000.

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