JAMA Publishes Positive Results of Alkermes' Phase III Study of Vivitrex in Alcohol Dependent Patients

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Once-monthly Injection of Vivitrex(R) Demonstrated Significant Reduction in Heavy Drinking in Conjunction with Counseling

CAMBRIDGE, Mass.--(BUSINESS WIRE)--April 5, 2005-- Alkermes, Inc. (Nasdaq: ALKS) today announced the publication of results from the Phase III clinical study of Vivitrex(R) (naltrexone long-acting injection), which showed that a once-monthly dose of Vivitrex in combination with counseling significantly reduced the median number of heavy drinking days in alcohol dependent patients from 19 days per month to three days per month. The study, led by nationally known investigators, is published in this week's issue of the Journal of the American Medical Association ("JAMA")(1) and represents one of the largest, most comprehensive clinical trials evaluating the use of medication for the treatment of alcohol dependence. The majority of the patients enrolled in the trial were actively and heavily drinking at study initiation.

"The results of the Vivitrex study show how pharmacotherapy has the potential to advance the standard of care for alcohol dependence. Alcoholism is a disease that causes physiological changes in the brain, and the use of medication is a logical foundation for counseling and recovery efforts," stated James C. Garbutt, M.D., Professor of Psychiatry at University of North Carolina at Chapel Hill and lead author of the publication. "Reducing heavy drinking improves patients' health as well as their day-to-day functioning in work and home lives."

"Today's report originated from an NIH/NIAAA Small Business Innovation Research (SBIR) award to a small pharmaceutical company with a good idea. Their findings represent a significant public-private accomplishment and are a major step in the long, careful process of medications development and approval," stated Raye Litten, Ph.D., Associate Director, Division of Treatment and Recovery Research of the National Institute on Alcohol Abuse and Alcoholism ("NIAAA"). "Most important, the finding that injectable naltrexone is effective and well tolerated offers hope to physicians and patients for an important new tool for the treatment of alcohol dependence."

Study Design

The Phase III multi-center, double-blind, placebo-controlled clinical trial included 624 patients, more than 90% of whom were actively drinking at study enrollment. Patients were randomized to receive either Vivitrex 380 mg (N = 205), Vivitrex 190 mg (N = 210), or a placebo (N = 209) administered by injection in a clinical setting once per month for six months. All patients received standardized, low-intensity counseling consisting of 12 sessions during the six-month study.

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. Of the various measures of drinking behavior, heavy drinking shows the highest correlation with negative life consequences such as impaired driving, interpersonal problems and injuries(2).

Study Results

In the overall study population, Vivitrex was associated with a statistically significant reduction in the rate of heavy drinking relative to placebo (P = 0.0245). Additional highlights for the Vivitrex 380 mg treatment group include:

- The median number of heavy drinking days was reduced from 19 days per month in the month prior to the study to three days per month over the six months of Vivitrex treatment.
- Vivitrex was associated with a reduction in heavy drinking within the first month of treatment, and this response was maintained over the six-month treatment period.

Safety Results

- Vivitrex was generally well tolerated.
- Adverse events were predominantly mild and decreased over time. The three most common adverse events reported were nausea, headache and fatigue.
- Injection site reactions were more commonly seen in the treatment groups versus the placebo group. Approximately 1% of subjects discontinued participation in the trial due to injection site reaction.

"This study demonstrated that Vivitrex achieved a significant reduction in heavy drinking in a broad U.S. population of alcohol dependent patients, the majority of whom were actively drinking when they entered the study," stated David Gastfriend, M.D., Vice President of Medical Affairs at Alkermes. "In addition, this publication in a prestigious, peer-reviewed journal represents an important milestone for the Company as we work toward our goal to bring Vivitrex to patient care."

About Alcohol Dependence

In the U.S., approximately 18 million people are dependent on or abuse alcohol(3) and an estimated 2.3 million adults seek treatment each year(4). Even among individuals currently seeking treatment, the majority relapse(5). Taking prescribed medication, an important determinant in therapeutic outcomes(6), is particularly challenging for patients with addictive disorders such as alcohol dependence(7). Alcohol is causally related to more than 60 medical conditions, including heart disease, liver disease, infectious disease, and cancer(8, 9), and contributes to more than 100,000 deaths in the U.S. each year(10). In addition, alcohol abuse and dependence accounts for approximately $134 billion in lost earnings annually(11).

About Vivitrex

Vivitrex is a long-acting, injectable form of naltrexone that is under development as a once-monthly treatment regimen utilizing Alkermes' proprietary Medisorb(R) drug-delivery technology. Naltrexone is a non-addictive, non-aversive agent that binds to opioid receptors in the brain. In people with alcohol dependence, it is believed that this blockade diminishes craving for alcohol and leads to a greater ability to resist urges to drink excessively(12). On March 31, 2005, Alkermes submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for marketing approval of Vivitrex. The Vivitrex clinical development program has been funded in part with a Small Business Innovation Research Program grant from the National Institute on Alcohol Abuse and Alcoholism ("NIAAA").

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 1999, including, but not limited to, the potential marketing approval of Vivitrex. 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 the FDA accepts the NDA submission for Vivitrex and whether Vivitrex will ultimately receive marketing approval. 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.

Note: Alkermes will host a conference call at 8:30 a.m. EDT on Wednesday, April 6, 2005. The conference call may be accessed by dialing (866) 206-6154 for domestic callers and (703) 639-1107 for international callers. The conference call ID number is 683460. Additionally, the call will be webcast on the investor relations section of Alkermes' website at www.alkermes.com and archived on the site until Wednesday, April 13, 2005 at 5:00 p.m. EDT.

A replay of the conference call will be available from 11:30 a.m. on Wednesday, April 6, 2005 through Friday, April 13, 2005 at 12:00 p.m. EDT and may be accessed by dialing (888) 266-2081 for domestic callers and (703) 925-2533 for international callers. The replay access code is 683460.

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