Study of Sustained Efficacy and Tolerability of Vivitrex -- Naltrexone Long-Acting Injection -- after 18 Months of Treatment Presented At APA

May 23, 2005

Vivitrex(R) Demonstrated a Long-term Treatment Effect in Conjunction with Counseling in Alcohol Dependent Patients

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 23, 2005-- Alkermes (Nasdaq: ALKS) today announced positive results from the Phase III, open-label, 12-month extension study of Vivitrex(R) (naltrexone long-acting injection) in alcohol dependent patients. Findings from the study, presented today at the American Psychiatric Association (APA) Annual Meeting in Atlanta, Georgia, showed that Vivitrex and counseling led to a sustained reduction in heavy drinking over an 18-month treatment period among patients who had completed the six-month Phase III efficacy trial ("main trial") and enrolled in an open-label 12-month extension study. Over eighty-five percent of patients who completed the main trial chose to participate in the extension study.

"Alcohol dependence is a chronic, relapsing disease. We were pleased to see that in this study, Vivitrex led to a sustained reduction in heavy drinking over an extended treatment period," stated David Gastfriend, M.D., Vice President of Medical Affairs at Alkermes. "These results complement the data from our Phase III efficacy study and reinforce our belief that pharmacotherapy has the potential to advance the standard of care for alcohol dependence."

Vivitrex Phase III Extension Study Results

The results of the extension study were presented in a poster entitled "Durability of Effect of Long-Acting Injectable Naltrexone." This Phase III, open-label extension study was designed to characterize outcomes of patients who received long-term treatment with Vivitrex following completion of the main trial. The results of the main trial were recently reported in the Journal of the American Medical Association(1). The objectives of the extension study were to examine the durability of the treatment effect and to continue the evaluation of the tolerability of Vivitrex administered by intramuscular injection once-monthly in adults with alcohol dependence. The trial included 332 patients who had completed the six-month main trial. Patients who received Vivitrex 380 mg (N = 115) or Vivitrex 190 mg (N = 102) during the main trial were assigned the same dose in the extension study. Patients who received a placebo injection in the main trial received either Vivitrex 380 mg (N = 60) or Vivitrex 190 mg (N = 55), based on the volume of placebo injection administered in the main trial.

Of the 332 patients who chose to participate in the extension study, 140 (42%) patients received all study injections, and 109 (78%) patients who completed the extension study chose to participate in a further continuation phase.

Key findings from this open-label study included:

- The subgroup of patients who continued on active treatment with Vivitrex 380 mg showed a sustained reduction in levels of heavy drinking over the 12-month extension study. For this subgroup, the median number of heavy drinking days over the six months of Vivitrex treatment in the main trial was similar to the median number of heavy drinking days over the 12 months of Vivitrex treatment in the extension study (2.6 days per month and 1.6 days per month, respectively). Heavy drinking is defined as five or more drinks per day for men and four or more drinks per day for women.
- Patients treated with placebo injection and counseling in the main trial who switched to Vivitrex 380 mg in the extension study showed a reduction in the number of heavy drinking days, from 5.2 days per month over six months of placebo treatment in the main trial to 1.8 days per month over 12 months of Vivitrex treatment in the extension study.
- Vivitrex was generally well tolerated over the 18-month period. The most common adverse events observed during the extension study were headache, nasopharyngitis, and upper respiratory tract infections.

Three additional posters are being presented on results from the Vivitrex clinical development program during the APA meeting:

- "Effects of Lead-in Drinking/Treatment Goal with Long-acting Naltrexone" will be presented Monday, May 23, from 3:00 pm - 5:00 pm by Stephanie O'Malley, Ph.D., Professor of Psychiatry and Director of the Division of Substance Abuse Research at Yale School of Medicine.
- "Correlation of Serum Gamma-Glutamyl Transferase with Alcohol Consumption" will be presented Monday, May 23, from 3:00 pm - 5:00 pm by Peter Martin, M.D., Professor of Psychiatry, Pharmacology Director of Division of Addiction Medicine at Vanderbilt University Medical Center.
- "Effect of Long-Acting Injectable Naltrexone on Quality of Life," will be presented Thursday, May 26, from 12:00 pm - 2:00 pm by Henry Kranzler, M.D., Professor of Psychiatry, Associate Scientific Director of the Alcohol Research Center, and Assistant Dean for Clinical Research at University of Connecticut School of Medicine.

About Alcohol Dependence

In the U.S., approximately 18 million people are dependent on or abuse alcohol(2) and an estimated 2.3 million adults seek treatment each year(3). Even among individuals currently seeking treatment, the majority relapse(4). Taking prescribed medication, an important determinant in therapeutic outcomes(5), is particularly challenging for patients with addictive disorders such as alcohol dependence(6). Alcohol is causally related to more than 60 medical conditions, including heart disease, liver disease, infectious disease, and cancer(7)(8), and contributes to more than 100,000 deaths in the U.S. each year(9). In addition, alcohol abuse and dependence accounts for approximately $134 billion in lost earnings annually(10).

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(11). 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.

Note: Alkermes will host a reception and discussion of Vivitrex, focusing on data from the Phase III efficacy trial and Phase III extension study in alcohol dependent patients. The event will be webcast live from the APA Conference on Monday, May 23, 2005 at 5:30 pm EDT. The presentation may be accessed under the investor relations tab at www.alkermes.com and will be archived for 7 days.

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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(3)Substance Abuse and Mental Health Services Administration Survey, 2002.

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