Alkermes Completes Enrollment in Long-Term Safety Study of Vivitrex, Naltrexone, Long-Acting Injection for the Treatment of Alcohol Dependence

April 22, 2004

CAMBRIDGE, Mass.--(BUSINESS WIRE)--April 22, 2004--Alkermes, Inc. (NASDAQ: ALKS) today announced the completion of patient enrollment in its post Phase III safety study for Vivitrex(R) (naltrexone) long-acting injection. More than 400 patients suffering from alcohol dependence, opiate dependence and mixed substance dependence from 24 centers are currently enrolled in the open label, 12 month long safety study. An interim safety analysis will be completed in approximately six months.

The Phase III safety study is designed to evaluate the long-term safety of naltrexone long-acting injection (380mg) administered by intramuscular injection once-monthly in adults with alcohol and opiate dependence. Study participants are randomized to receive either a once-monthly intramuscular injection of Vivitrex (380mg) or oral naltrexone 50mg daily. All patients enrolled in the study also receive psychosocial support for the duration of the study. Safety will be evaluated based on adverse events, injection site assessments, serum chemistry, hematology, urinalysis and physical examination.

"After finding positive preliminary results in the Vivitrex Phase III clinical trial, the completion of patient enrollment in this safety study serves as the next critical milestone in our plan to bring Vivitrex to market and improve outcomes for alcohol-dependent patients," said Richard Pops, Chief Executive Officer of Alkermes.

Vivitrex is a proprietary long-acting formulation of naltrexone based on Alkermes' Medisorb(R) injectable, extended-release technology. By providing an extended-release dose administered once-monthly, rather than daily, Vivitrex is designed to facilitate compliance with treatment regimens and thereby may improve outcomes for alcohol-dependent patients.

Phase III Clinical Trial Preliminary Results

The preliminary results of the Phase III clinical trial for Vivitrex, first announced in December 2003, demonstrated a statistically significant reduction in heavy drinking in alcohol dependent patients. Patients received psychosocial support and once-monthly injections of Vivitrex 380 mg, Vivitrex 190 mg, or placebo for a six-month period. In the overall study population, patients treated with Vivitrex 380 mg experienced approximately a 25 percent reduction in the rate of heavy drinking relative to placebo which was statistically significant. Gender played a dominant role in the study results. Two thirds of the patients enrolled in the study were male, which is representative of the alcohol dependent population. In male patients, there was a statistically significant reduction in the rate of heavy drinking among the treatment groups relative to placebo, with approximately a 48 percent reduction in males treated with Vivitrex 380 mg and approximately a 25 percent reduction in males treated with Vivitrex 190 mg. Female patients treated with 190 mg and 380 mg showed no significant difference from placebo.

Adverse Events

Vivitrex was generally well tolerated by patients in the Phase III trial. In patients receiving Vivitrex, the three most common adverse events reported during the six-month study were nausea, headache and fatigue. Injection site reactions were more commonly seen in the treatment groups versus the placebo group. Less than 2% of the patients discontinued in the trial due to injection site reaction.

About Alcohol Dependence

Approximately 18 million people in t he United States are dependent on or abuse alcohol(1) and it is estimated that two thirds of the alcohol-dependent population in the United States is comprised of men.(2) Alcohol dependence not only affects the individual. Almost half of United States adults - 76 million people - have been exposed to alcoholism in the family.(3) Alcohol dependence causes more than 100,000 deaths in the United States each year(4) and a study by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) found that alcohol dependence costs Americans approximately $185 billion per year in lost earnings, medical bills and trauma, such as car accidents or accidental injury.(5)

About Vivitrex

Vivitrex is a long-acting, injectable form of naltrexone that was developed utilizing Alkermes' proprietary Medisorb drug-delivery technology. Using the Medisorb technology, naltrexone is encapsulated in microspheres made of a biodegradable polymer that dissolves slowly and releases drug at a controlled rate following intramuscular injection. 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

Alkermes, Inc. is an emerging pharmaceutical company developing products based on its sophisticated drug delivery technologies to enhance therapeutic outcomes. Our areas of focus include: controlled, extended-release of injectable drugs utilizing our ProLease(R) and Medisorb delivery systems and the development of inhaled pharmaceutical products based on our proprietary AIR(R) pulmonary delivery system. Our business strategy is twofold. We partner our proprietary technology systems and drug delivery expertise with many of the world's finest pharmaceutical companies and also develop novel, proprietary drug candidates for our own account. In addition to our Cambridge, Massachusetts headquarters and research and manufacturing facilities, we operate research and manufacturing facilities in 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, statements regarding the timing of our interim safety analysis, our clinical trial and marketing plans and partnering

strategy. Although we believe that such statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, various factors may cause our actual results to differ materially from our expectations. These include whether we encounter unexpected delays, side effects or drop out rates in our clinical trials, whether and when a new drug application will be submitted to the FDA and be accepted on a timely basis or at all; whether the FDA will interpret clinical and preclinical data in a manner consistent with our interpretations of such data; whether Vivitrex, if approved, would be accepted by the market; whether we can successfully assemble an effective specialty sales force to market Vivitrex, if approved; whether we enter into any collaboration with a third party to market or fund the development and/or commercialization of Vivitrex; and whether we can complete manufacturing scale up successfully and in a timely manner or manufacture Vivitrex in the quantities demanded. For further information with respect to factors that could cause actual results to differ from expectations, reference is made to the reports filed by us with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended. The statements in this release are current as of the date of this release and we undertake no obligation to update or modify these statements based on changed circumstances or otherwise unless required by law.

---

(1) Grant, B., et al. Epidemiologic Bulletin No. 35: Prevalence of DSM-IV alcohol abuse and dependence, United States 1992. Alcohol Health & Research World 18(3):243-248, 1994.

(2)Grant, B., et al.

(3) National Center for Health Statistics {NCHS}, Advance Data, USDHHS, No.205, September, 1991, p.1.

(4) J McGinnis & W Foege, "Actual Causes of Death in the United States," Journal of the American Medical Association, Vol. 270, No. 18, November, 1993, p.2208.

(5) Harwood, H. Updating Estimates of the Economic Costs of Alcohol Abuse in the United States: Estimates, Update Methods, and Data. Report prepared by The Lewin Group for the National Institute on Alcohol Abuse and Alcoholism, 2000. Based on estimates, analyses, and data reported in Harwood, H.; Fountain, D.; and Livermore, G. The Economic Costs of Alcohol and Drug Abuse in the United States 1992. Report prepared for the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Department of Health and Human Services. NIH Publication No. 98-4327. Rockville, MD: National Institutes of Health, 1998.

CONTACT: Rebecca Peterson
Director, Corporate Communications
Alkermes, Inc.
617-583-6378

SOURCE: Alkermes, Inc.