Alkermes Begins Phase III Trial of Vivitrex in Alcohol Dependent Patients; Alkermes Also Begins Opiate Challenge Clinical Study

April 1, 2002

CAMBRIDGE, Mass., Apr 1, 2002 (BW HealthWire) -- Alkermes, Inc., (NASDAQ: ALKS) today announced that it has initiated the pivotal clinical trial of Vivitrex(TM), the company's proprietary injectable extended-release formulation of naltrexone. The multi-center trial will test the efficacy and safety of repeated doses of Vivitrex administered monthly to alcohol-dependent patients. The clinical trial follows the successful completion of a multi-dose, multi-center safety and pharmacokinetic clinical assessment of the product in alcohol-dependent volunteers conducted in the second half of 2001.

Alkermes intends to enroll approximately 400 patients in the double-blind, placebo-controlled study. The study is being conducted at 25 centers in the United States. After the initial 6-month treatment period, an extension study is planned to obtain long-term safety data. Dosing of patients has already begun.

"This pivotal trial of Vivitrex is designed to provide definitive information regarding the safety and efficacy of an extended release formulation of naltrexone in alcohol-dependent patients," said Richard F. Pops, Chief Executive Officer of Alkermes. "The ultimate goal of our clinical development program is to provide patients, their families and caregivers with an effective alternative to daily naltrexone."

Concurrently Alkermes began a multi-center clinical study of Vivitrex in opiate users. The study is designed to test safety and pharmacokinetics of a range of doses.

Naltrexone is an FDA-approved drug used for the treatment of alcohol dependence and is currently available in a daily oral dosage form. Vivitrex is a proprietary formulation of naltrexone based on Alkermes' Medisorb(R) injectable extended-release drug delivery technology and is designed to provide once-a-month dosing. Vivitrex is designed to enhance patient compliance by removing the need for daily dosing and providing therapeutic drug levels consistently over a one-month period.

In the U.S., 14 million people suffer from alcohol dependency or meet diagnostic criteria for alcohol abuse disorder. More than half of all adult Americans have direct family experience with alcohol problems, costing American society more than 100,000 lives and approximately $185 billion each year.(1)

Medisorb is Alkermes' proprietary injectable extended-release drug delivery technology. The technology is based on the encapsulation of drugs into small polymeric microspheres that degrade slowly and release drugs at a controlled rate following subcutaneous or intramuscular injection. Alkermes is developing Medisorb product candidates in collaboration with pharmaceutical and biotechnology companies and on its own. The company's lead Medisorb product candidate is Risperdal Consta(TM), a formulation of Janssen Pharmaceutica's antipsychotic drug Ripserdal(R). A new drug application (NDA) for Risperdal Consta was submitted to the U.S., Food and Drug Administration on August 31, 2001 by Johnson & Johnson Pharmaceutical Research & Development, which conducted the clinical development program. Vivitrex is Alkermes' first proprietary product candidate based on the Medisorb technology.

The Vivitrex project has been funded in part with Federal funds from the National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health.

Alkermes is a leader in the development of products based on sophisticated drug delivery technologies. The company has several areas of focus, including (i) controlled, sustained release of injectable drugs lasting several days to several weeks, utilizing its ProLease(R) and Medisorb technologies and (ii) the development of pharmaceutical products based on proprietary pulmonary drug delivery technologies utilizing its AIR(TM) technology. Alkermes' first product, Nutropin Depot(R), was launched in the United States by its partner, Genentech, Inc., in June 2000. Nutropin Depot is a long-acting form of Genentech's recombinant human growth hormone using Alkermes' ProLease technology. In addition to its Cambridge, Massachusetts headquarters, research and manufacturing facilities, Alkermes operates research and manufacturing facilities in Ohio and a medical affairs office in Cambridge, England.

Certain statements set forth above may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Although Alkermes believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, there can be no assurance that: (i) the preliminary data will be predictive of the final data from this clinical trial or future clinical trials, (ii) the FDA will allow future clinical trials to be conducted or (iii) further development of the product candidate will move at the same pace as has been achieved to date.

Alkermes' business is subject to significant risks and there can be no assurance that actual results of the company's development activities and its results of operations will not differ materially from its expectations. For information with respect to other factors that could cause actual results to differ from expectations, reference is made to the reports filed by the Company with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

(1) http://www.niaaa.nih.gov/about/statement2002.htm

The National Institute on Alcohol Abuse and Alcoholism, a component of the National Institutes of Health, U.S. Department of Health and Human Services

CONTACT: Alkermes, Inc.

Rebecca Peterson
Director, Investor Relations
(617) 583-6378

URL: http://www.businesswire.com
Today's News On The Net - Business Wire's full file on the Internet
with Hyperlinks to your home page.