



Alkermes Completes Enrollment in Phase III Clinical Trial of Vivitrex-R- for the Treatment of Alcohol Dependence

March 31, 2003

CAMBRIDGE, Mass., Mar 31, 2003 (BUSINESS WIRE) -- Alkermes, Inc., (NASDAQ: ALKS) today announced the completion of patient enrollment in its pivotal Phase III clinical trial for Vivitrex(R). Vivitrex is a proprietary formulation of naltrexone based on Alkermes' Medisorb(R) injectable, extended-release technology designed to provide once monthly dosing for the treatment of alcohol dependence.

The Phase III clinical trial, a randomized, placebo-controlled, double-blind study, is designed to confirm the safety and efficacy of Vivitrex in alcohol-dependent patients during a six-month period. Patient enrollment started in February 2002 at 24 centers in the U.S. and has reached a total enrollment of more than 600 patients. Following the six-month treatment period, patients may enter an extension study which will collect long-term safety data for an additional 12 months. The extension study is well underway with more than 180 patients entered to date.

"We are extremely pleased that the clinical trial is fully enrolled as it shows the strong interest from investigators and patients," said Richard Pops, Chief Executive Officer of Alkermes. "The completion of patient enrollment represents an important milestone in reaching our ultimate goal of developing Vivitrex into an innovative product that offers significant therapeutic benefits for alcohol-dependent patients."

Prevalent Condition

In the U.S., it is estimated that 17 million people suffer from alcohol dependency or meet diagnostic criteria for alcohol abuse disorder(1). More than half of all adult Americans have direct family experience with alcohol problems. Alcohol abuse is the cause of more than 100,000 deaths in America each year(2). According to a study by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA), in 1998, alcohol dependence and abuse cost Americans - private citizens, corporations, local and state governments and the federal government - a total of \$184.6 billion(3).

The Vivitrex clinical development program has been funded in part with federal funds from the NIAAA.

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. Alkermes plans to commercialize Vivitrex using a specialty sales force to call on addiction specialists and substance abuse centers. Alkermes is in discussions with potential partners about broader commercialization of the product in the U.S., Europe and for other indications such as opiate abuse.

Alkermes is developing products using the Medisorb technology on its own and in partnership with pharmaceutical and biotechnology companies. The company's lead Medisorb product is Risperdal Consta(TM), which was developed in collaboration with its partner, Janssen-Cilag, S.A., a wholly-owned subsidiary of Johnson & Johnson. Approved for sale in 18 countries, Risperdal Consta is the only long-acting injectable atypical antipsychotic available. In the U.S., discussions are ongoing with the Food and Drug Administration (FDA), which last year issued a non-approvable letter based on questions related to certain aspects of the pre-clinical data.

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(R) delivery systems and the development of inhaled pharmaceutical products based on our proprietary Advanced Inhalation Research, Inc. ("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. 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 the Phase III trial of Vivitrex will successfully demonstrate efficacy sufficient to seek regulatory approval; Alkermes' ability to assemble a specialty sales force; the effectiveness of such a sales force in marketing Vivitrex if it is approved; whether regulatory approvals will be received for Risperdal Consta, particularly in the U.S.; actions by our partners with regard to marketing and regulatory filings; the outcome of clinical and preclinical work we are pursuing; decisions by the FDA or foreign regulatory authorities regarding our product candidates; potential changes in cost, scope and duration of clinical trials; and decisions we make about the timing and scope of proprietary product development. 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.

(1) Alkermes, Inc. forecasting data, 2002.

(2) National Institute on Alcohol Abuse and Alcoholism, epidemiology data on file.

(3) Harwood, H. The Economic Costs of Alcohol and Drug Abuse in the United States: Estimates, Update Methods, and Data. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute on Drug Abuse and National Institute on Alcohol Abuse and Alcoholism. December 2000.

Alkermes, Inc.

Rebecca Peterson, 617/583-6378