



Alkermes Reports Alcohol Dependent Patients Treated with Vivitrex Reduced Heavy Drinking Days by 50 Percent in Phase II Clinical Trial

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Results of clinical trial presented at the 26th Annual Scientific Meeting of the Research Society on Alcoholism

CAMBRIDGE, Mass., Jun 23, 2003 (BUSINESS WIRE) -- Alkermes, Inc. (Nasdaq: ALKS) today presented results from a Phase II clinical study that showed that patients treated with once-monthly injections of Vivitrex(R), in combination with psychosocial therapy, experienced a 50 percent reduction in heavy drinking days compared to patients receiving placebo injections in combination with psychosocial therapy. Vivitrex, an extended-release formulation of naltrexone using Alkermes' proprietary Medisorb(R) technology, is currently being further evaluated in more than 600 patients in a Phase III study for the treatment of alcohol dependence.

In the multicenter, randomized, double-blind, placebo-controlled Phase II study, 30 patients were randomized to receive either Vivitrex 400 mg or a matching dose of placebo, administered intramuscularly once a month for four months. After four treatment cycles, the mean percentage of heavy drinking days reported during the study was 11.7 percent in the Vivitrex-treated group versus 25.3 percent in the placebo-treated group.

"By definition, alcohol-dependent patients are difficult to treat and vulnerable to relapse, which is why it is encouraging to see how well patients responded to treatment in this study," commented Bankole Johnson, M.D., Ph.D., the study's lead investigator, and Wurzbach Distinguished Professor, Departments of Psychiatry and Pharmacology, University of Texas Health Science Center at San Antonio. "The once-monthly convenience of Vivitrex eliminates the need for daily treatment and encourages patient adherence, which ultimately may help them remain abstinent for longer periods of time."

Phase III Trial Fully Enrolled

Vivitrex is currently being studied in a Phase III multicenter, randomized, double blind, placebo-controlled clinical study at 24 U.S. centers. The study completed enrollment of more than 600 patients in late March 2003, and initial results are expected in the first half of 2004. Following a six-month treatment period, patients can enter a 12-month extension study that will allow collection of long-term safety data.

"The rapid enrollment in the Phase III study reflects the need for new treatments that improve the lives of people with alcohol dependence," stated Elliot Ehrich, M.D., Vice President, Science and Development and Chief Medical Officer at Alkermes. "We believe Vivitrex has the potential to fulfill that unmet need."

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, and federal, state and local governments - a total of \$184.6 billion.(3)

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 over an extended period following intramuscular injection.

In clinical studies to date, Vivitrex has generally been well tolerated, and adverse events reported have been mild to moderate in severity. The most commonly reported adverse events have included headache, nausea and dry mouth.

The Vivitrex development program has been funded in part with federal funds from the 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(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 for the Company to seek regulatory approval; Alkermes' ability to supply sufficient quantities of commercial product; 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(TM), 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.

(Note to editors: The poster presentation, titled, "A Phase II Study of Extended Release Naltrexone (Vivitrex(R)) in Alcohol Dependent Patients," will be presented at 4:00 to 7:00 pm on Monday, June 23, 2003 during the 26th Annual Scientific Meeting of the Research Society on Alcoholism in Florida.)

(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.

SOURCE: Alkermes, Inc.

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