Alkermes Reports Positive Results of Phase II Clinical Trial of VIVITREX for Alcohol Dependency At Annual Meeting of the American College of Neuropsychopharmacology

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CAMBRIDGE, Mass., Dec 10, 2001 (BW HealthWire) --

Positive Outcome Prompts Decision to Proceed with Phase III Studies

Alkermes, Inc. (NASDAQ: ALKS) announced today the presentation of positive results from a Phase II clinical trial of VIVITREX(TM) (Medisorb(R) Naltrexone), the company's proprietary injectable sustained-release formulation of naltrexone. Data from the clinical trial were presented Sunday, December 9, 2001 at the 40th Annual Meeting of the American College of Neuropsychopharmacology (ACNP) in Waikoloa, Hawaii. These data summarized the safety, tolerability and preliminary efficacy of repeat doses of VIVITREX in alcoholic patients. The positive results of this Phase II study support Alkermes' decision to proceed to larger scale efficacy studies of VIVITREX.

The poster presentation, entitled, "A Phase II Study of VIVITREX in Alcohol-Dependent Adults," was based on a multi-center, randomized, double-blind, placebo-controlled clinical trial, conducted at five treatment centers in the U.S. and Europe. The study evaluated the safety and tolerability of intramuscular repeat dose administration of VIVITREX in 30 alcohol-dependent patients, while also exploring outcome measures related to drinking activity.

Preliminary data after four treatment cycles indicate that, on average, patients treated with VIVITREX plus psychosocial therapy (N=25) experienced a 50% reduction in heavy drinking days when compared with patients treated with placebo injections with psychosocial therapy (N=5). VIVITREX was well tolerated. The most common adverse events, headache and nausea, were seen in a similar proportion of VIVITREX and placebo treated patients.

"Oral naltrexone is a currently approved treatment regimen for alcohol and opiate dependence. However, the daily dosing regimen for the treatment of alcohol abuse often results in patient compliance issues," according to Bankole Johnson, M.D., Ph.D., Wurzbach Distinguished Professor, Departments of Psychiatry and Pharmacology, University of Texas -- Health Science Center at San Antonio, a principal investigator for the Alkermes study. "By eliminating the need for daily compliance, VIVITREX has the potential to become an important therapeutic agent in the treatment of alcoholism. The results of this study underscore this potential."

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)

"We are very pleased with the outcome of this trial. This Phase II study provides evidence that naltrexone can be effectively formulated as a sustained-release preparation and administered over multiple courses of therapy," said Elliot Ehrich, M.D., Vice President, Medical Affairs at Alkermes. "The outcome of this trial will serve as the basis for proceeding to Phase III studies in 2002."

VIVITREX, Alkermes' proprietary formulation of naltrexone, provides a sustained drug level over a one month period eliminating the need for daily medication. The VIVITREX project has been partially funded by the National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health.

Medisorb is one of Alkermes' proprietary injectable sustained-release drug delivery technologies. The technology is based on the encapsulation of drugs into small polymeric microspheres, which 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 leading Medisorb product candidate, Janssen Pharmaceuticas' antipsychotic drug RISPERDAL Consta(TM), is pending approval with the U.S. Food and Drug Administration.

Alkermes is a leader in the development of products based on sophisticated drug delivery technologies. We have several areas of focus, including (i) controlled, sustained-release of injectable drugs lasting several days to several weeks, using our ProLease(R) and Medisorb(R) technologies and (ii) the development of pharmaceutical products based on our proprietary AIR(TM) pulmonary technology. In addition to our 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 we believe that such statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, there can be no assurance that: (i) we will be permitted by regulatory authorities to undertake a Phase III study or that it will not be delayed, (ii) clinical trials of our product candidates will be successful and completed on a timely basis, if at all, (iii) pending applications with the U.S. FDA will receive approval on a timely basis, if at all, (iv) our partners will continue development of any product candidate to the point of receiving marketing approval from regulatory authorities, or (v) our product candidates, if approved, will be commercialized successfully.

Alkermes' business is subject to significant risks and there can be no assurance that actual results of its 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 Alkermes with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

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

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