Alkermes Begins Multi-Center Clinical Trial of Medisorb Naltrexone in Alcohol-Dependent Patients

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CAMBRIDGE, Mass.--(BW HealthWire)--April 3, 2001--Alkermes, Inc., (NASDAQ: ALKS) today announced the initiation of enrollment in the second clinical trial of Medisorb(R) Naltrexone, the company's proprietary injectable sustained release formulation of naltrexone. The trial will test the safety, tolerability and pharmacokinetics of repeated doses of Medisorb Naltrexone administered monthly to alcohol-dependent patients. The clinical trial follows the successful completion of a single-dose safety and pharmacokinetic clinical assessment of the drug in normal volunteers conducted in the second half of 2000.

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

Alkermes intends to enroll 30 patients in the double-blind, placebo-controlled study. The study is being conducted at centers in the U.S. and Europe. In addition to assessing safety, tolerability and pharmacokinetics of Medisorb Naltrexone, the study will assess treatment paradigms and outcome measurements for use in subsequent pivotal efficacy trials.

"We have moved quickly to build on the results from our first clinical trial of Medisorb Naltrexone and to enroll in this multi-dose study in alcohol-dependent patients," said Richard F. Pops, Chief Executive Officer of Alkermes. "Our goal is to develop a sustained release formulation of naltrexone that provides patients, their families and caregivers with significant advantages over the current daily oral dosage form."

Medisorb is Alkermes' proprietary injectable sustained 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 a formulation of Janssen Pharmaceutica's antipsychotic drug RISPERDAL(R) that has recently completed Phase III clinical trials. Medisorb Naltrexone is Alkermes' first proprietary product candidate based on the technology.

The Medisorb Naltrexone 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(TM), 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.

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