Alkermes Announces Successful Completion of Phase I Clinical Trial for Inhaled Form of Epinephrine; Proprietary Product Candidate Therapeutic Advantages to Patients

November 6, 2002

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 6, 2002--Alkermes, Inc. (Nasdaq: ALKS) today announced the successful completion of a Phase I safety study in healthy volunteers designed to investigate a proprietary, inhaled formulation of epinephrine called AIR(TM) Epinephrine. The inhaled formulation offers a non-invasive, alternative drug delivery method for epinephrine in the treatment of anaphylaxis, a sudden, potentially life-threatening allergic reaction. Current epinephrine therapy is primarily delivered by a self-administered injection. AIR Epinephrine was developed using Alkermes' novel AIR technology for the pulmonary delivery of dry powder aerosols composed of large porous particles.

The clinical trial was a dose escalation study in healthy volunteers designed to test the safety, tolerability and pharmacokinetics of single and repeat doses of inhaled epinephrine compared to the standard epinephrine delivered with an intramuscular auto-injection system. The findings demonstrated systematic bioavailability of the inhaled formulation and delivery of clinically active dosage levels of epinephrine. AIR Epinephrine was generally well tolerated.

"These clinical results are very encouraging and set the stage for further development," said Elliot Ehrich, M.D., Vice President of Medical Affairs at Alkermes. "Anaphylaxis is a serious condition with increasing incidence in the United States and abroad. We believe that AIR Epinephrine represents a new paradigm in the treatment of anaphylaxis through rapid delivery of clinically relevant doses of epinephrine to the respiratory tract and systemic circulation. With AIR Epinephrine patients carry a convenient, compact inhaler to reliably and simply self-administer epinephrine without a needle."

In addition to AIR Epinephrine, the Company's proprietary pipeline includes Vivitrex(TM), an extended release formulation of naltrexone, an approved product for the treatment for alcohol dependence and opiate abuse. Alkermes is currently in Phase III clinical trials with Vivitrex for the treatment of alcohol dependence. Alkermes' proprietary product pipeline resulted from the company's strategy to identify product for which it can improve the method of dosage and drug delivery and thereby offer therapeutic benefits for patients.

About Anaphylaxis

Anaphylaxis is a serious, acute allergic reaction that often requires emergency room treatment and may affect as much as 15% of the population in the United States(1). The condition occurs when the immune system creates specific disease-fighting antibodies toward a substance that is normally harmless, such as nuts, shellfish, dairy products, penicillin and bee stings. Anaphylaxis contributes to, or complicates, the course of one out of every 2,700 hospitalized patients and, if not treated properly and promptly, can in some cases result in death. The incidence of anaphylaxis is expected to rise as the number of allergic reactions in the United States and many European countries progressively increases.

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") 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, research and manufacturing facilities, we operate research and manufacturing facilities in Ohio.

Alkermes' AIR drug delivery system is based on a novel concept, published in Science magazine in 1997, that relatively large, low-density drug particles can be inhaled into the lungs with high efficiency from simple inhalers. These particles have distinct physical characteristics with several potential advantages over other inhalation delivery systems. The AIR system utilizes a small, convenient delivery device, can deliver a wide range of drug doses, and has the potential to provide sustained-release drug delivery.

Many 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 current knowledge of our business and operations, our business is subject to significant risks and various factors may cause our actual results to differ materially from our expectations. These include, among others: (i) Johnson & Johnson Pharmaceutical Research and Development, LLC received a non-approvable letter for Risperdal Consta(TM) from the FDA and the issues raised therein may not be resolved in a timely fashion, if at all; (ii) our collaborators could elect to terminate or delay programs at any time; (iii) our products and our product candidates, if approved for marketing, may not be successfully commercialized or produce significant revenues; (iv) our product development efforts, even with regard to late-stage product candidates, may not produce safe, efficacious, approvable or commercially viable products; (v) we will need to spend substantial funds to become profitable and will, therefore, continue to incur losses for the foreseeable future; and (vi) we could incur difficulties or set-backs in obtaining the substantial additional funding required to continue research and development programs and clinical trials. 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, including our Annual Report on Form 10-K.

(1) Neugut AI, et al, Anaphylaxis in the United States: An Investigation into its Epidemiology, Arch Intern Med., Jan. 2001, Vol. 161, pp. 15-21.

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