Alkermes Presents Positive Clinical Data for Inhaled Form of Epinephrine at American Academy of Allergy, Asthma and Immunology Meeting

March 22, 2004

Inhaled Formulation Offers Non-injection Alternative for Treatment of Anaphylaxis

CAMBRIDGE, Mass.--(BUSINESS WIRE)--March 22, 2004-- Alkermes, Inc. (Nasdaq: ALKS) today presented the results of a Phase I clinical study of AIR(R) Epinephrine, the Company's proprietary, inhaled formulation of epinephrine, at the annual American Academy of Allergy, Asthma and Immunology (AAAAI) meeting in San Francisco. In the study, AIR Epinephrine demonstrated rapid systemic delivery associated with clinically meaningful pharmacodynamic responses in normal volunteers, in addition to confirming the safety profile. The product was generally well tolerated and there were no serious adverse events in the study.

The presentation, "A Placebo-and Active-Comparator Controlled Dose Escalation Study of the Pharmacokinetics, Pharmacodynamics, and Safety of Inhaled Large Porous Particle AIR Epinephrine in Normal Volunteers," assesses the systemic pharmacokinetic and pharmacodynamic profile of AIR Epinephrine compared to intramuscular injection and subcutaneous injection of epinephrine and placebo. 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 epinephrine delivered with an intramuscular auto-injection system.

"These clinical results are very encouraging, demonstrating rapid delivery of clinically relevant doses of epinephrine to the respiratory tract and systemic circulation," said Elliot Ehrich, M.D., Vice President of Science and Development and Chief Medical Officer at Alkermes. "We believe that AIR Epinephrine could offer patients at risk of anaphylaxis a new treatment approach, allowing them to carry a convenient, compact inhaler to reliably and simply self-administer epinephrine without a needle."

Inhaled epinephrine could eliminate the need for patient self-injection, for the emergency self-treatment of anaphylaxis, a sudden, potentially life-threatening allergic reaction. Inhaled epinephrine may also provide optimized clinical outcomes by effecting rapid systemic delivery of epinephrine via central pulmonary circulation combined with topical delivery to the upper and lower respiratory tract.

AIR Epinephrine is an investigational inhaled dry powder formulation using Alkermes' AIR technology, which utilizes drug particles that can be delivered using small, simple inhalers. AIR technology accommodates high drug doses, provides systemic delivery as well as local or targeted delivery to the lung, offers rapid onset of action and the potential for prolonged release. Alkermes is investigating several potential applications for its AIR technology including pulmonary insulin and pulmonary human growth hormone.

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 sting venom. 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. Alkermes expects the incidence of anaphylaxis to rise because the number of allergic reactions in Western civilizations is increasing(2).

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 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.

(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.

(2) Hershe, Gurjit K. Khurana, Is it all in our genes? The "mite-y" truth, Journal of Allergy and Clinical Immunology, March 2004, Vol. 113 No. 3.

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including whether AIR Epinephrine will be approved by regulatory authorities and be used in place of injectable epinephrine and whether the market for anaphylaxis products will grow. These statements are neither promises nor guarantees, but are subject to risks and uncertainties that could cause our actual results to differ materially from our expectations. These factors include whether further clinical trials have similar results; the timing and cost of the program; the standards that regulatory agencies will use in reviewing our development program; whether a new drug application will be submitted to the FDA and whether such submission will be accepted; and whether AIR Epinephrine, if approved, will produce significant revenues for the Company. 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. The statements in this release are current as of the date of this release only, and Alkermes undertakes no obligation to update or modify these statements based on changed circumstances or otherwise unless required by law.

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