Alkermes Presents Results of Pulmonary Insulin Clinical Trial At Annual Meeting of the American Diabetes Association

June 25, 2001

CAMBRIDGE, Mass., Jun 25, 2001 (BW HealthWire) -- Alkermes, Inc., (NASDAQ: ALKS) announced today the presentation of results from a Phase I clinical trial of the company's inhaled insulin, based on Alkermes' AIR(TM) pulmonary drug delivery system. These findings were presented in the President's Poster Session on Sunday, June 24, 2001 at the American Diabetes Association in Philadelphia, Pennsylvania. Findings will be presented again today, Monday, June 25th, at the General Poster Session.

The study was a single administration study in healthy volunteers designed to test the safety, tolerability, pharmacokinetics and pharmacodynamics of a wide range of insulin doses. The findings were presented in the poster presentation entitled 'Time-Action Profile of a New Rapid Acting Inhaled Insulin with High Biopotency' based on research by Alkermes' scientists. The poster showed that our insulin formulation showed rapid onset of therapeutic action, dose dependent glucose lowering ability and competitive biopotency.

"This is the first demonstration of therapeutically relevant dosing efficiency for insulin using a simple inhaler to deliver an engineered formulation of insulin to the deep lung," said James Wright, Ph.D., Senior Vice President of Alkermes. "We are now moving aggressively in collaboration with our partner Eli Lilly and Company to further develop these advanced formulations."

In April 2001, Alkermes and Eli Lilly and Company signed a broad, mutually exclusive agreement to develop inhaled formulations of insulin including short- and long-acting insulin and other potential products for the treatment of diabetes based on Alkermes' AIR pulmonary drug delivery system.

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.

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(R) technologies and (ii) the development of pharmaceutical products based on proprietary pulmonary drug delivery technologies utilizing its AIR 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.

(abstract follows)

Time-Action Profile of a New Rapid Acting Inhaled Insulin with High Biopotency

C. OSBORN1, R. BATYCKY2, A. VERMA1, A. ILLEPERUMA2, C. TUSEK3, S. BOTT3, L. HEINEMANN3, T.HEISE3. 1Alkermes Europe Ltd., UK; 2Alkermes Inc., MA, USA; 3PROFIL, Institute for Metabolic Research, Germany.

This study investigated the time-action profile and dose-response relationship of a rapid acting inhaled insulin formulation (AI). The aerodynamic properties of the highly porous insulin powder have been engineered to achieve relatively high biopotency from a simple breath-actuated, and potentially disposable inhaler.

The pharmacodynamic (PD) properties of AI at 84, 168 and 294 IU were investigated by means of a euglycemic glucose clamp (clamp level 5.0 mmol/L, continuous i.v. insulin infusion of 0.15 mU/kg/min, clamp duration 12 hours post-dosing) in comparison with 15 IU s.c. insulin lispro (IL) and with 15 IU s.c. regular insulin (RI) in 12 healthy male volunteers (non smokers, age 28.9 +/- 5.9 years, BMI 23.5+/- 2.3 kg/m2).

AI showed a faster onset of action compared with s.c. insulin (early Tmax 50%(min): 29 (84 IU), 35 (168 IU), 33 (294 IU), 41 (IL) and 70 (RI) (p