Lilly and Alkermes Initiate Phase 3 Safety Study for Inhaled Insulin

July 19, 2005

CAMBRIDGE, Mass., Jul 19, 2005 (BUSINESS WIRE) -- - Companies Begin Comprehensive Phase 3 Clinical Trials Program -

Alkermes, Inc. (NASDAQ: ALKS) and Eli Lilly and Company (NYSE: LLY) today announced the initiation of a Phase 3 clinical trial required for registration for their inhaled insulin system, which is being investigated as an innovative treatment option for diabetes. The goal of this study is to more fully define the safety and efficacy of the Lilly/Alkermes inhaled insulin system in patients with diabetes. This study marks the start of a comprehensive Phase 3 clinical program, including pivotal efficacy studies and additional long-term safety studies in both type 1 and type 2 patients.

"New therapies are vital to combat the growing epidemic of diabetes around the world," said Carlos Paya, vice president, Lilly Research Laboratories. "For more than 80 years, Lilly has been a worldwide leader in treating diabetes, and the Lilly/Alkermes Alliance is focused on developing new treatment options that may enable diabetes patients to achieve better blood sugar control, a key aspect in managing diabetes."

"The initiation of this Phase 3 study is an important milestone for our inhaled insulin program and affirms our goal of bringing forward an innovative approach for the treatment of diabetes," said Richard Pops, chief executive officer of Alkermes. "We and Lilly are highly encouraged by the clinical data compiled from our inhaled insulin studies conducted to date and are committed to conducting the additional studies needed to further establish the safety and efficacy of inhaled insulin."

This Phase 3 open-label, randomized study is designed to evaluate the safety and efficacy of the Lilly/Alkermes inhaled insulin system compared to injected pre-meal insulin in 400 non-smoking patients with type 1 diabetes. Patients will be treated for 24 months with a two-month follow-up period. The 70-site study began July 18, in the United States and will enroll patients in the United States, Canada, Belgium, Croatia, Hungary and India.

A second multi-center, global safety study to support registration will begin in August. This Phase 3 open-label, randomized study is designed to evaluate the safety and efficacy of the Lilly/Alkermes inhaled insulin system compared to injected insulin in 600 type 1 and type 2 diabetes patients with mild-to-moderate asthma or mild-to-moderate chronic obstructive lung disease. Patients will be treated for 12 months with a two-month follow-up period. The trial will enroll patients at 140 sites in North America (United States, Canada and Mexico), South America (Argentina, Chile and Columbia), Europe (Bulgaria, Croatia and Hungary) and Asia-Pacific (India, the Philippines, Singapore, Taiwan and Thailand).

Lilly/Alkermes Inhaled Insulin Program

In June 2005, Lilly and Alkermes presented Phase 2 clinical data at the 65th Annual Scientific Sessions of the American Diabetes Association which showed that patients using the Lilly/Alkermes inhaled insulin system achieved blood sugar levels similar to patients treated with injected insulin. In addition, inhaled insulin and injected insulin were generally well tolerated over the three-month treatment period. There were no clinically meaningful differences between the inhaled and injected insulin groups with respect to fasting blood glucose, carbon monoxide lung diffusing capacity (DLCO), and severe hypoglycemia.

Lilly and Alkermes established an alliance in 2001 to develop an inhaled insulin system that delivers human insulin inhalation powder (known as HIIP), based on Alkermes' AIR(R) pulmonary drug delivery technology. The Lilly/Alkermes program is focused on developing an innovative treatment option that can help address the challenges associated with managing type 1 and type 2 diabetes. Nearly two-thirds of patients on therapies are not achieving treatment goals for controlling blood sugar.(1) The HIIP delivery system uses a small, simple inhaler that fits in the palm of a hand.

About Diabetes

Diabetes affects an estimated 194 million adults worldwide and more than 18 million in the United States. Approximately 90 to 95 percent of those affected have type 2 diabetes, a condition where the body does not produce enough insulin and/or the cells in the body do not respond normally to insulin. Diabetes is the fifth leading cause of death by disease in the United States and costs approximately $132 billion per year in direct and indirect medical expenses. Type 2 diabetes usually occurs in adults over the age of 40, but is increasingly common in younger people. Nearly two-thirds of patients on therapies are not achieving treatment goals for controlling blood sugar.

About Alkermes, Inc.

Alkermes, Inc. is a pharmaceutical company that develops products based on sophisticated drug delivery technologies to enhance therapeutic outcomes in major diseases. The Company's lead commercial product is the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, and is marketed worldwide by Janssen-Cilag ("Janssen"), a wholly owned subsidiary of Johnson & Johnson. The Company's lead proprietary product candidate, Vivitrex(R) (naltrexone long-acting injection), is being developed as a once-monthly injection for the treatment of alcohol dependence. The Company has a pipeline of extended-release injectable products and pulmonary drug products based on its proprietary technology and expertise. Alkermes' product development strategy is twofold: the Company partners its proprietary technology systems and drug delivery expertise with several of the world's finest pharmaceutical companies and it also develops novel, proprietary drug candidates for its own account. The Company's headquarters are in Cambridge, Massachusetts, and it operates research and manufacturing facilities in Massachusetts and Ohio.

(1) Saydah SH, Fradkin J, Cowie CC. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. JAMA 2004;291:335-342.

Lilly's Leadership in Diabetes

Through a long-standing commitment to diabetes care, Lilly provides patients with breakthrough treatments that enable them to live longer, healthier and fuller lives. Since 1923, Lilly has been the industry leader in pioneering therapies to help health care professionals improve the lives of people with diabetes, and research continues on innovative medicines to address the unmet needs of patients. For more information about Lilly's current diabetes products visit www.lillydiabetes.com.

About Lilly

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

This press release contains forward-looking statements about the investigational compound inhaled insulin, the clinical trial program for inhaled insulin and its efficacy and rate of adoption by patients, and reflects Lilly's and Alkermes' current beliefs. However, as with any pharmaceutical product under development, there are substantial risks and uncertainties in the process of development and regulatory review. There is no guarantee that clinical trials for the product, if commenced, will be completed, that the product will receive regulatory approvals, or that the regulatory approval will be for the indication(s) anticipated by the companies. There is also no guarantee that the product will enhance current levels of glucose control or prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's and Alkermes' filings with the United States Securities and Exchange Commission. Lilly and Alkermes undertake no duty to update forward-looking statements.

SOURCE: Alkermes, Inc.

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