Lilly and Alkermes Initiate Additional Phase 3 Study for Inhaled Insulin as Part of Comprehensive Registration Program

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INDIANAPOLIS, Ind. and CAMBRIDGE, Mass.--(BUSINESS WIRE)--April 26, 2006--Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced the initiation of a Phase 3 clinical trial required for registration for their AIR(R) Inhaled Insulin System(1) (AIR system), which is being investigated as an innovative treatment option for type 1 and type 2 diabetes. This study in type 2 diabetes patients is designed to compare A1C -- an average measure of blood sugar (glucose) over a three-month period -- between the AIR system and injectable pre-meal insulin. The study is part of the comprehensive Phase 3 pivotal program that began in July 2005.

"Diabetes is a major worldwide health threat, and there is a significant need for new therapies that can help patients better manage their blood sugar," stated Dr. Carlos Paya, vice president of Lilly Research Laboratories and leader of Lilly's pulmonary development platform. "This Phase 3 study is an important component of our comprehensive registration program for our AIR system and affirms our commitment to bringing forward a new treatment option for patients with diabetes."

"This clinical study represents a continuation of our efforts to fully assess the safety, efficacy and therapeutic benefits the AIR system may offer," stated Elliot Ehrich, chief medical officer of Alkermes. "We and Lilly anticipate continued progress in the AIR(R) Inhaled Insulin program throughout this year."

This Phase 3 open-label, noninferiority study is designed to evaluate whether the AIR system is at least as effective in improving glucose control as injected pre-meal insulin. Approximately 400 insulin-naive patients with type 2 diabetes who are taking at least one oral antidiabetic medication will be randomized to one of the two treatment groups. The efficacy of the AIR system will be assessed for six months, and the safety of the AIR system will continue to be evaluated during an additional six and 18-month period.

Lilly/Alkermes Inhaled Insulin Program

Lilly and Alkermes are conducting Phase 3 clinical trials for an inhaled insulin system (known as the AIR system) that delivers insulin via inhalation 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. The AIR system uses a small, simple inhaler that fits in the palm of a hand. For more information about the Phase 3 trials, visit www.lillytrials.com.

About Diabetes

Diabetes affects an estimated 194 million adults worldwide and an estimated 20.8 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. Type 2 diabetes usually occurs in adults over the age of 40, but is increasingly common in younger people. 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. Nearly two-thirds of patients on therapies are not achieving treatment goals for controlling blood sugar(2). Diabetes is associated with an increased risk for a number of serious complications, including heart disease, stroke, amputation, blindness and kidney failure.

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.

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 products include: the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, marketed worldwide by Janssen-Cilag ("Janssen"), a wholly owned subsidiary of Johnson & Johnson; and VIVITROL(TM) (naltrexone for extended-release injectable suspension), the first and only once-monthly injectable medication approved 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.

This press release contains forward-looking statements about the investigational compound inhaled insulin, and the clinical trial program for inhaled insulin for the treatment of diabetes, 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 the clinical trials for inhaled insulin will enroll fully or, if fully enrolled, be completed successfully; or that the product will receive regulatory approval. 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.

(1)AIR(R) is a registered trademark of Alkermes, Inc.

(2) 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.

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