Lilly and Alkermes Complete Patient Enrollment for Phase 3 Safety Study for Inhaled Insulin for the Treatment of Diabetes

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Companies on Track With Phase 3 Clinical Program of AIR(R) Inhaled Insulin System

INDIANAPOLIS and CAMBRIDGE, Mass., June 5 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced the completion of patient enrollment in a pivotal safety study required for registration for their AIR(R)(1) Inhaled Insulin System (AIR insulin system), which is being investigated as an innovative treatment option for diabetes. The goal of the study is to more fully define the safety and efficacy of the AIR insulin system in patients with type 1 diabetes. This study is part of a comprehensive Phase 3 clinical program that began in July 2005 which includes pivotal efficacy studies and additional long-term safety studies in both type 1 and type 2 diabetes patients.

"Diabetes has reached epidemic proportions and is becoming one of the world's most prevalent, costly and debilitating diseases. There continues to be a significant need for new therapeutic options that can help patients gain control of their blood sugar and achieve better, overall health outcomes," said Dr. Carlos Paya, vice president of Lilly Research Laboratories and leader of Lilly's pulmonary development platform. "This Phase 3 study is a vital component of the registration program for our AIR insulin system, and we expect to make continued progress in our Phase 3 trials throughout the year."

"We are pleased to have completed enrollment in this Phase 3 study, which is a key step in our progress toward the New Drug Application filing for the AIR insulin system," said Elliot Ehrich, chief medical officer of Alkermes. "We and Lilly are highly encouraged by the clinical data compiled from our AIR insulin system studies conducted to date and are committed to conducting the 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 AIR insulin system compared to injected pre-meal insulin in nearly 400 non-smoking patients with type 1 diabetes. Patients are being treated for 24 months with a two-month follow-up period. Pulmonary safety tests (PFTs) are used to assess safety. The trial will also evaluate the noninferiority of AIR(R) Insulin (AIR insulin) to injected insulin lispro with respect to A1C levels -- the average measure of blood glucose over a three month period. At this time, all patients have been enrolled and randomized to receive treatment. The 66-site study began enrolling patients in July 2005 in the United States, Canada, Belgium, Croatia, Hungary and India.

In addition, the Companies recently initiated another study required as part of the Phase 3 pivotal trial program. This Phase 3 open-label, noninferiority study is designed to evaluate whether the AIR insulin system is at least as effective in improving glucose control as injected pre-meal insulin over six months. 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 insulin system will be assessed at six months, and the safety will be evaluated at 12 and 24 months.

Lilly/Alkermes Inhaled Insulin Program

Lilly and Alkermes are conducting Phase 3 clinical trials for an inhaled insulin system, known as the AIR(R) Inhaled Insulin System, (AIR insulin 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 insulin system uses a small, simple inhaler that fits in the palm of a hand. For more information, visit http://www.lillytrials.com.

About Diabetes

Diabetes affects an estimated 194 million adults worldwide and an estimated 20.8 million in the United States. 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.

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.

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 http://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 http://www.lilly.com.

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. P-LLY

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