# Alkermes Announces Lilly Decision to Proceed with Late-Stage Clinical Development Program for Inhaled Insulin

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 10, 2004--Alkermes, Inc. (Nasdaq: ALKS) announced today that Eli Lilly and Company ("Lilly") has made a positive product decision and will proceed with significant investment for the further development of an inhaled formulation of insulin. The decision follows the successful execution of several critical steps: the completion and analysis of data from a Phase 2 study; the achievement of commercial manufacturing powder production scale-up; and the development and testing of the commercial pulmonary insulin inhaler system. Development activities will include both clinical trials and additional manufacturing activities for the inhaler system and the production facility.

A recently completed Phase 2 clinical trial for inhaled insulin using Alkermes' AIR(R) technology showed that patients with type 1 diabetes achieved glycemic control levels similar to injected insulin. The trial was a multi-center, cross-over design study with 120 patients with type 1 diabetes receiving an inhaled formulation of insulin using AIR technology for a three-month period. Inhaled insulin had a rapid onset of action and was well tolerated with adverse events similar in both treatment arms.

"We're delighted that the strength of the clinical data and our achievement of commercialization milestones provided the basis of the decision by Lilly to move forward with further development for inhaled insulin," said Elliot Ehrich, M.D., Chief Medical Officer at Alkermes. "We look forward to initiating additional clinical studies that will bring us another step closer to developing an important new treatment for the growing number of people living with diabetes."

The inhaled insulin delivery system is based on Alkermes' AIR pulmonary drug delivery technology, which uses a small, easy-to-use, inhaler designed to provide drug delivery for a wide range of drug doses. Alkermes and Lilly have collaborated on the inhaled insulin program since 2001 to develop an innovative treatment option for people with diabetes.

About Diabetes

Diabetes is a group of diseases characterized by high levels of blood glucose resulting from defects in insulin production, insulin action, or both. According to the American Diabetes Association ("ADA"), diabetes can be associated with serious complications and premature death, but people with diabetes can take steps to control the disease and lower the risk of complications (Source ADA). Additionally, the World Health Organization ("WHO") lists diabetes as one of the leading causes of mortality worldwide. Approximately 193 million people around the world have diabetes, and this number is expected to double to 330 million by the year 2025 (Source International Diabetes Federation).

About Alkermes

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, Risperdal(R) Consta(TM) ((risperidone) long-acting injection), is the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia and is marketed worldwide by Janssen, a division of Johnson & Johnson. The company's lead proprietary product candidate, Vivitrex(R) ((naltrexone) long-acting injection), is a once-a-month injection for the treatment of alcohol dependence. Alkermes has a pipeline of extended-release injectable and pulmonary drug products based on its proprietary technology and expertise. The company's headquarters are in Cambridge, Massachusetts, and it operates research and manufacturing facilities in Massachusetts and Ohio. For more information on Alkermes, please visit www.alkermes.com.

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements with respect to the potential of inhaled formulations of insulin based on our AIR pulmonary drug delivery technology, planned clinical trials and manufacturing activities, and growth in patient population. 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 the timing and cost of future clinical trials and whether further clinical trials will have similar results; decisions by our partner with respect to the program which are outside of our control, risks related to development, formulation and scale-up of inhaled insulin, risks associated with our ability to manufacture inhaled insulin, risks associated with registration of our inhaled insulin product with health authorities, risks associated with competitive products and treatment and whether inhaled formulations of insulin, if approved, will produce significant revenues. 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 we undertake no obligation to update or modify these statements based on changed circumstances or otherwise unless required by law.

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