Exenatide LAR Data Support Initiation of Phase 2 Multi-Dose Study in 2005

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SAN DIEGO, INDIANAPOLIS, and CAMBRIDGE, Mass., Nov. 2 -- PRNewswire-FirstCall/ -- Amylin Pharmaceuticals, Inc., (Nasdaq: AMLN - News), Eli Lilly and Company (NYSE: LLY - News) and Alkermes, Inc. (Nasdaq: ALKS - News) today announced the decision to initiate a Phase 2 multi-dose study of exenatide LAR (long-acting release) in patients with type 2 diabetes using a once-a-week dosing regimen. The multi-dose study is expected to begin in the first quarter of 2005. Data from the ongoing Phase 2 single-dose study have demonstrated sustained release of exenatide with no dose-limiting side effects. The injection has been well tolerated.

The single-dose study includes approximately 60 subjects with type 2 diabetes who were failing to achieve adequate glucose control using diet and exercise with or without metformin. Subjects are randomized to receive a single subcutaneous injection of exenatide LAR at one of four doses or placebo, and are observed for 90 days. At this time, dosing and follow-up observation of the final exenatide LAR dosage group is ongoing.

The goal of the exenatide LAR program is to develop a sustained release, subcutaneous injection of exenatide. Exenatide LAR is based on Alkermes' proprietary Medisorb® injectable sustained release drug delivery technology.

About Exenatide

Exenatide is the first in a new class of drugs called incretin mimetics being investigated for the treatment of type 2 diabetes and appears to exhibit many of the same effects as the human incretin hormone GLP-1. In June 2004, a New Drug Application (NDA) for exenatide was submitted to the Food and Drug Administration (FDA) for regulatory approval.

About Diabetes

Diabetes affects an estimated 194 million adults worldwide(1) and more than 18 million in the United States(2). Approximately 90-95 percent of those affected have type 2 diabetes, in which the body does not produce enough insulin and the cells in the body do not respond normally to the insulin. According to the US Center for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60 percent of diabetes patients do not achieve target A1C levels with their current treatment regimen. According to the ADA, patients with A1Cs above target are more likely to develop diabetes-related complications, such as kidney disease, blindness and heart disease(3).

About Amylin, Lilly and Alkermes

Amylin Pharmaceuticals is committed to improving the lives of people with diabetes and other metabolic diseases through the discovery, development and commercialization of innovative, cost-effective medicines. Further information on Amylin Pharmaceuticals and its pipeline in metabolism is available at www.amylin.com.

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.

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® 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-Cilag, a division of Johnson & Johnson. The Company's lead proprietary product candidate, Vivitrex® [(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. Additional information about Alkermes is available at www.alkermes.com.

This press release contains forward-looking statements, which involve risks and uncertainties within the meaning of the Private Securities Litigation Reform Act of 1995. There can be no assurance that actual results will not differ materially from the forward-looking statements discussed in this press release. These forward-looking statements include risks and uncertainties that current or future clinical trials will confirm the results referred to in this release or that the multi-dose trial will commence when planned, risks and uncertainties inherent in the collaboration with and dependence upon Lilly, Amylin and/or Alkermes; risks and uncertainties regarding the drug discovery and development process, including whether exenatide LAR will receive regulatory approvals or prove to be commercially successful. These and additional risks and uncertainties are described more fully in Amylin, Lilly and Alkermes' filings with the United States Securities and Exchange Commission, such as their Annual Reports on Form 10-K for the fiscal year ended December 31, 2003 under the heading "Risk Factors Related to Our Business," their subsequently filed Quarterly Reports on Form 10-Q, and Amylin's recently filed Form S-3. The parties undertake no duty to update forward-looking statements.

(1) The International Diabetes Federation Diabetes Atlas. Available at: http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3 87B73F80BC22682A. Accessed August 31, 2004.

(2) American Diabetes Association. Available at: http://www.diabetes.org/about-diabetes.jsp. Accessed August 31, 2004.

(3) Saaddine JB, Engelgau MM, Beckles GL, Gregg EW, Thompson TJ, Narayan KM. A diabetes report card for the United States: Quality of care in the 1990s. Ann Intern Med. 2002; 136:565-574.

Source: Amylin Pharmaceuticals, Inc.