August 22, 2005

Once Weekly Exenatide LAR Well Tolerated and Improved Glucose Control

- Preliminary Results From Phase 2 Study Announced -

SAN DIEGO, INDIANAPOLIS and CAMBRIDGE, Mass., Aug 22, 2005 /PRNewswire-FirstCall via COMTEX/ -- Amylin Pharmaceuticals, Inc., (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced results from the ongoing Phase 2 multi-dose study of a long-acting release (LAR) formulation of BYETTA(TM) (exenatide) injection in patients with type 2 diabetes.

The study was designed to assess the safety, tolerability and pharmacokinetics of exenatide LAR given once a week. After 15 weeks, both doses of exenatide LAR were well tolerated and expected therapeutic blood levels of exenatide were achieved. Dose-dependent improvements in hemoglobin A1C (A1C) and weight were observed.

A1C, a measure of glucose control, improved approximately 2 percent for subjects receiving the high dose of exenatide LAR, compared to placebo. At the beginning of the study, the average A1C of study participants was approximately 8.5 percent. The decrease in A1C was progressive with no evidence of a plateau at week 15. Twelve of the 14 high-dose subjects who entered the study with an A1C greater than 7 percent achieved an A1C of 7 percent or less at 15 weeks. None of the 14 subjects receiving placebo achieved that target. The American Diabetes Association recommends a target A1C of less than 7 percent.

Fasting blood glucose concentrations were reduced by approximately 50 mg/dL for subjects in the high dose group compared to those receiving placebo. Subjects in this group experienced an average weight reduction of approximately 9 pounds compared to those receiving placebo.

The most common adverse event was mild nausea, which occurred in approximately 20 percent of subjects in the high dose group compared to approximately 7 percent in the placebo group. No severe gastrointestinal side effects were reported. No severe hypoglycemia was reported, and no subjects receiving exenatide LAR withdrew because of adverse events.

This Phase 2, randomized, placebo-controlled, double-blind study includes 45 subjects with type 2 diabetes who were not achieving adequate glucose control using diet and exercise with or without metformin. Subjects were randomized to receive 15 once-weekly subcutaneous injections of exenatide LAR at one of two doses or placebo. At this time, study participants have completed the active dosing period. Subjects will be observed for an additional 12 weeks with follow-up observations and data analyses ongoing. The companies anticipate that the full study results will be presented in a future scientific forum.

On April 28, 2005, the Food and Drug Administration (FDA) approved twice daily exenatide under the trade name BYETTA(TM) (exenatide) injection for use by people with type 2 diabetes who are unsuccessful at controlling their blood sugar levels despite using commonly prescribed oral medications metformin, a sulfonylurea, or both. Amylin, Lilly, and Alkermes are working together to develop a sustained release, subcutaneous injection of exenatide for the treatment of type 2 diabetes based on Alkermes' proprietary Medisorb(R) injectable long-acting release drug delivery technology. Exenatide LAR has not been approved by the FDA for marketing in the United States.

About BYETTA

BYETTA is the first in a new class of drugs for the treatment of type 2 diabetes called incretin mimetics and exhibits many of the same effects as the human incretin hormone glucagon-like peptide-1 (GLP-1). GLP-1, secreted in response to food intake, has multiple effects on the intestine, liver, pancreas and brain that work in concert to improve blood sugar (1).

About Incretin Mimetics

Incretin mimetics is a new class of treatment in the fight against diabetes. An incretin mimetic works to mimic the anti-diabetic or glucose-lowering actions of naturally occurring human hormones called incretins. These actions include stimulating the body's ability to produce insulin in response to elevated levels of blood sugar, inhibiting the release of a hormone called glucagon following meals, slowing the rate at which nutrients are absorbed into the bloodstream and reducing food intake. BYETTA is the first FDA-approved agent of this new class of medications.

About Diabetes

Diabetes affects an estimated 194 million adults worldwide (2) and more than 18 million in the United States (3). Approximately 90-95 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 (3). Diabetes is the fifth leading cause of death by disease in the United States (4) 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 (3).

According to the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60 percent of diabetes patients do not achieve target A1C levels (less than 7.0 percent according to American Diabetes Association guidelines (5)) with their current treatment regimen (6).

Important Safety Information for BYETTA(TM) (exenatide) injection

BYETTA(TM) (exenatide) injection improves blood sugar control in patients with type 2 diabetes who are taking metformin, a sulfonylurea, or both. BYETTA is not a substitute for insulin in patients whose diabetes requires insulin treatment. BYETTA is not recommended for use in patients with severe problems digesting food or those who have severe disease of the stomach or kidney. BYETTA has not been studied in children or pregnant women.

When BYETTA is used with a medicine that contains a sulfonylurea, low blood sugar (hypoglycemia) is a possible side effect. To reduce this possibility, the dose of sulfonylurea medicine may need to be reduced while using BYETTA. Other common side effects with BYETTA include nausea, vomiting, diarrhea, dizziness, headache, feeling jittery, and acid stomach. Nausea is most common when first starting BYETTA, but decreases over time in most patients. BYETTA may reduce appetite, the amount of food eaten, and body weight. No changes in dose are needed for these side effects. These are not all the side effects with BYETTA. A health care provider should be consulted about any side effect that is bothersome or does not go away.

For complete safety profile and other important prescribing considerations, visit www.BYETTA.com.

About Amylin, Lilly, and Alkermes

Amylin Pharmaceuticals is a biopharmaceutical company committed to improving lives through the discovery, development and commercialization of innovative medicines. Amylin has developed and gained approval for two first-in-class medicines for diabetes, SYMLIN(R) (pramlintide acetate) injection and BYETTA(TM) (exenatide) injection. Further information on Amylin Pharmaceuticals and its pipeline in metabolism is available at www.amylin.com.

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.

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 is the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia. 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.

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 be completed 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 the LAR version of BYETTA 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, including Amylin's recently filed Form 10-Q. The parties undertake no duty to update forward-looking statements.

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