Study Demonstrated Once-Weekly Exenatide LAR Improved Glucose Control in Patients with Type 2 Diabetes

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WASHINGTON, D.C., June 10 /PRNewswire-FirstCall/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced detailed results from a safety and efficacy study of the long-acting release (LAR) formulation of BYETTA(R) (exenatide) injection. Data from the study demonstrated that 86 percent of patients using the higher of two doses of the once-weekly formulation of exenatide were able to achieve recommended levels of glucose control, as measured by hemoglobin A1C (A1C) with an average improvement of approximately 2 percent compared to placebo. These study findings were presented today at the 66th Annual Scientific Sessions of the American Diabetes Association (ADA) in Washington, D.C.

The study was conducted in 45 patients with type 2 diabetes unable to achieve adequate glucose control with metformin or a diet and exercise regimen. The patients received a once-weekly subcutaneous injection of exenatide LAR (either 0.8 mg or 2.0 mg) or placebo. After 15 weeks of treatment there was a 12-week safety monitoring period during which no study medication was administered.

Dose-dependent improvements in A1C and weight loss were observed at 15 weeks. At the beginning of the study, the average A1C of study participants was approximately 8.5 percent. In subjects receiving the 2.0 mg dose of exenatide LAR, the average reduction in A1C was 1.7 percent compared to an increase of 0.4 percent in the placebo group. Those receiving the 0.8 mg dose improved with an average decrease in A1C of 1.4 percent.

In patients administered 0.8 mg or 2.0 mg of exenatide LAR, 33 percent and 86 percent achieved A1C levels of 7 percent or less, respectively. None of the patients given placebo achieved this target level of glucose control. A1C is a reflection of a person's average glucose level over approximately three months and often used by doctors as a measure of glucose management.

Fasting blood glucose levels were reduced by an average of 39 mg/dL in the 2.0 mg arm and 43 mg/dL in the 0.8 mg arm compared to an average increase of 18 mg/dL in the placebo group at week 15. Average fasting blood glucose level at the beginning of the study was 179 mg/dL. Patients who received 2.0 mg of exenatide LAR also experienced average reductions in body weight of 8.4 pounds at week 15 with no evidence of plateau at this point in time; body weight remained essentially unchanged for the 0.8 mg and placebo groups. The most frequent adverse event was mild nausea, experienced by 27 percent of subjects in the 2.0 mg dose group and 19 percent of subjects in the 0.8 mg dose group compared to 15 percent in the placebo group. No severe hypoglycemia was observed, and no subjects receiving either dose of exenatide LAR withdrew because of adverse events. These detailed findings supplement the preliminary results released in 2005.

"In this study, the long-acting formulation of exenatide improved glycemic and weight control and was well tolerated as a combination therapy with metformin or as stand alone therapy with diet and exercise," said Dennis Kim, MD, Senior Director, Medical Affairs, Amylin Pharmaceuticals and an author of the study. "These early results suggest exenatide LAR can be clinically beneficial to patients with type 2 diabetes."

Exenatide LAR uses the proprietary Medisorb(R) drug-delivery technology developed by Alkermes. The technology encapsulates active medication into polymer-based microspheres that are injected into the body, where they degrade slowly -- gradually releasing the drug at a carefully controlled rate.

On April 28, 2005, the Food and Drug Administration (FDA) approved twice daily exenatide under the trade name BYETTA 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 incretin mimetic, a class of drugs for the treatment of type 2 diabetes. BYETTA 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 regulate blood sugar.(1)

Safety and Tolerability of BYETTA

Adverse events associated with BYETTA are generally mild to moderate in intensity. In clinical trials, the most frequently reported adverse event was mild-to-moderate, dose-dependent nausea. With continued therapy, the frequency and severity of nausea decreased over time in most patients.

Patients receiving BYETTA in combination with a sulfonylurea may be at a higher risk of hypoglycemia or low blood sugar. To reduce this risk, decreasing the dose of sulfonylurea may be considered. When patients begin taking BYETTA, the symptoms, treatment and conditions that predispose development of hypoglycemia should be explained to them, and the patient's usual instructions for hypoglycemia management should be reviewed and reinforced.

Patients should also be advised that treatment with BYETTA may lead to a reduction in appetite, food intake and/or body weight, and that there is no need to modify the dosing regimen due to such effects.

BYETTA is not a substitute for insulin in insulin-requiring patients. BYETTA should not be used in patients with type 1 diabetes. Use of BYETTA is not

recommended in patients with end-stage renal disease or severe renal impairment, or in patients with severe gastrointestinal disease. BYETTA should be used with caution in patients receiving oral medications that require rapid gastrointestinal absorption.

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

About Incretin Mimetics

Incretin mimetics is a distinct 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 incretin mimetic.

About Diabetes

Diabetes affects an estimated 194 million adults worldwide(2) and more than 20 million in the United States.(3) Approximately 90 to 95 percent of those affected have type 2 diabetes, a condition characterized by failure of the pancreatic beta cells to adequately respond to the increased demands for insulin that occur as a result of obesity-related insulin resistance.(4) Diabetes is the sixth leading cause of death by disease in the United States(3) 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 hemoglobin A1C levels (less than 7 percent according to ADA guidelines(5)) with their current treatment regimen.(6)

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(R) (exenatide) injection. Amylin is located in San Diego, California with over 1200 employees nationwide. Further information on Amylin Pharmaceuticals, its marketed products, 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 http://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, IN, 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.

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, which involve risks and uncertainties within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements are neither promises nor guarantees, and the businesses of Amylin, Lilly and Alkermes are subject to significant risks and uncertainties. Actual results may differ materially from the forward-looking statements discussed in this press release. These forward-looking statements include risks and uncertainties, including but not limited to, that current or future clinical trials will not confirm previous results; risks and uncertainties that Amylin will be able to complete manufacturing scale-up and construction and validation of its manufacturing facility on a timely basis, or at all; 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, be commercialized 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 their recently filed Form 10-Qs. The parties disclaim any obligation to update forward-looking statements.

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