Exenatide Once Weekly Provided Superior Glucose Control Compared To Lantus(R) in Head-to-Head DURATION-3 Study

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Significant Reductions in Weight and Fewer Reports of Hypoglycemia Compared to Lantus Also Observed

SAN DIEGO & INDIANAPOLIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 20, 2009-- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced positive results from a study comparing subjects randomized to either exenatide once weekly or Lantus® (insulin glargine). Patients randomized to exenatide once weekly experienced a statistically superior reduction in A1C, a measure of average blood sugar over three months, of 1.5 percentage points from baseline, compared to a reduction of 1.3 percentage points for Lantus after completing 26 weeks of treatment. At the end of the study, patients treated with exenatide once weekly achieved a mean A1C of 6.8 percent compared with a mean A1C of 7.0 percent in those treated with Lantus. Treatment with exenatide once weekly also produced a statistically significant difference in weight, with a mean weight loss of 5.8 pounds at 26 weeks, compared with a mean weight gain of 3.1 pounds for Lantus, a difference of 8.9 pounds between the treatments.

In addition, although patients treated with exenatide once weekly experienced a greater reduction in blood glucose than those treated with Lantus, they also reported significantly fewer episodes of confirmed hypoglycemia.

These intent-to-treat results were from DURATION-3, the third in a series of studies designed to test the superiority of exenatide once weekly, an investigational diabetes therapy, as compared to other diabetes medications. This 26-week open-label, clinical study compared exenatide once weekly to once-daily doses of Lantus in 467 patients with type 2 diabetes taking stable doses of metformin alone or in combination with a sulfonylurea. Exenatide once weekly was administered once a week in a fixed dose while Lantus was administered daily in a variable dose determined by patient blood sugar levels.

“Exenatide once weekly outperformed Lantus in this superiority study by meeting its primary endpoint,” stated Orville G. Kolterman, M.D., senior vice president of research and development, Amylin Pharmaceuticals. “Both treatment arms started with a baseline A1C of 8.3 percent and exenatide once weekly provided statistically significantly greater A1C reduction, weight loss versus weight gain and fewer episodes of hypoglycemia.”

More than 90 percent of patients completed the study. During the 26-week treatment period, the most frequently reported adverse events were upper respiratory infection, including nasopharyngitis, in both treatment arms, as well as gastrointestinal events, including nausea, in the exenatide once weekly treatment group. Patients treated with exenatide once weekly experienced less confirmed hypoglycemia; the incidence of hypoglycemia was 4 percent with exenatide once weekly versus 19 percent with Lantus for patients on metformin background therapy, and 20 percent with exenatide once weekly versus 44 percent with Lantus for patients on metformin and a sulfonylurea background therapy, differences that are statistically significant in both treatment groups.

Study Design

The 26-week open-label, superiority study included 467 subjects with type 2 diabetes who were not achieving adequate glucose control using metformin therapy alone or in combination with a sulfonylurea. Subjects were randomized to receive exenatide once weekly 2 milligrams by subcutaneous injection weekly or insulin glargine injections administered daily in a variable dose determined by patient blood sugar levels. There was no lead-in or wash-out period. The primary endpoint was reduction in A1C; secondary endpoints included change in body weight along with other parameters of glucose control, cardiovascular health, hypoglycemia and patient-reported outcomes. Subjects in both treatment groups are continuing in an open-ended extension study.

The companies plan to present the full data set at a major medical meeting and submit the data for publication.

About Diabetes

Diabetes affects more than 23 million people in the U.S. and an estimated 246 million adults worldwide.(i,ii) Approximately 90-95 percent of those affected have type 2 diabetes. Diabetes is the fifth leading cause of death by disease in the U.S. and results in approximately $174 billion per year in direct and indirect medical expenses.(iii)

According to the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60 percent of people with diabetes do not achieve their target blood sugar levels with their current treatment regimen.(iv) In addition, 85 percent of type 2 diabetes patients are overweight and 55 percent are considered obese.(v) Data indicate that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.(vi,vii)

About Amylin, Lilly and Alkermes

Amylin, Lilly and Alkermes are working together to develop exenatide once weekly, a subcutaneous injection of exenatide for the treatment of type 2 diabetes based on Alkermes’ proprietary technology for long-acting medications. Exenatide once weekly is not currently approved by any regulatory agencies.

Amylin Pharmaceuticals is a biopharmaceutical company committed to improving lives through the discovery, development and commercialization of innovative medicines. Amylin's research and development activities leverage the Company's expertise in metabolism to develop potential therapies to treat diabetes and obesity. Amylin is headquartered in San Diego, California.

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 healthcare professionals improve the lives of people with diabetes, and research continues on innovative medicines to address the unmet needs of patients.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Indiana, Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs.

Alkermes, Inc. is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. Alkermes' robust pipeline includes extended-release injectable, pulmonary and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Cambridge, Massachusetts, Alkermes has research facilities in Massachusetts and a commercial manufacturing facility in Ohio.

This press release contains forward-looking statements about Amylin, Lilly and Alkermes and the investigational drug, exenatide once weekly. Actual results could differ materially from those discussed or implied in this press release due to a number of risks and uncertainties, including the risk that exenatide once weekly may be affected by unexpected new data; safety and technical issues; clinical trials, including the clinical trial mentioned in this press release, not being completed in a timely manner, not confirming previous results, or not achieving the intended clinical endpoints; the DURATION-3 superiority study results potentially not being predictive of real world use including results relative to other diabetes medications; pre-clinical trials not predicting future results; label expansion requests or New Drug Application (NDA) filings, not being submitted in a timely manner; regulatory approval, including approval for exenatide once weekly, being delayed or not received; or manufacturing and supply issues. The potential for exenatide once weekly may also be affected by government and commercial reimbursement and pricing decisions, the pace of market acceptance, or scientific, regulatory and other issues and risks inherent in the development and commercialization of pharmaceutical products including those inherent in the collaboration with and dependence upon Amylin, Lilly and/or Alkermes. These and additional risks and uncertainties are described more fully in Amylin's, Lilly's and Alkermes' most recent SEC filings including their Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K. Amylin, Lilly and Alkermes undertake no duty to update these forward-looking statements.

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(i) "All About Diabetes." American Diabetes Association. Available at: http://www.diabetes.org/about-diabetes.jsp. Accessed July 13, 2009.

(ii) The International Diabetes Federation Diabetes Atlas. Available at: http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A. Accessed July 13, 2009.

(iii) "Direct and Indirect Costs of Diabetes in the United States." American Diabetes Association. Available at: http://www.diabetes.org/diabetes-statistics/cost-of-diabetes-in-us.jsp. Accessed July 13, 2009.

(iv) Saydah SH, Fradkin J, Cowie CC. "Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes." *JAMA*: 291(3), January 21, 2004.

(v) Bays HE, Chapman RH, Grandy S. The relationship of body mass index to diabetes mellitus, hypertension and dyslipidaemia: comparison of data from two national surveys. *Int J Clin Pract*. 2007;61:737-47.

(vi) Nutrition Recommendations and Interventions for Diabetes: a position statement of the American Diabetes Association. *Diabetes Care*. 2008;31 Suppl 1:S61-78.

(vii) Anderson JW, Kendall CW, Jenkins DJ. Importance of weight management in type 2 diabetes: review with meta-analysis of clinical studies. *J Am Coll Nutr*. 2003;22:331-9.

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