Press Release

Exenatide Once Weekly Provided Superior Glucose Control With Weight Loss Compared to Sitagliptin or Pioglitazone in Head-to-Head DURATION-2 Study

SAN DIEGO, INDIANAPOLIS and CAMBRIDGE, Mass., March 31, 2009 /PRNewswire-FirstCall via COMTEX/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced positive results from DURATION-2, the second 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 clinical study compared exenatide once weekly to maximum doses of sitagliptin or pioglitazone, two commonly prescribed oral diabetes medications, in 491 patients with type 2 diabetes taking stable doses of metformin. After completing 26 weeks of treatment, evaluable patients randomized to exenatide once weekly experienced a statistically significant reduction in A1C, a measure of average blood sugar over three months, of 1.7 percentage points from baseline, compared to a reduction of 1.0 percentage point for sitagliptin and 1.4 percentage points for pioglitazone. This finding represents a statistically significant benefit of exenatide once weekly over both sitagliptin and pioglitazone.

Treatment with exenatide once weekly also produced statistically significant differences in weight, with weight loss of 6.2 pounds at 26 weeks, compared with a loss of 1.9 pounds for sitagliptin, and a weight gain of 7.4 pounds for pioglitazone.

"Recognizing the importance of A1C control, it has become clear that health care providers need comparative data to better understand the relative value of therapeutic options," said Richard Bergenstal, M.D., executive director of the International Diabetes Center. "A once-weekly therapy that helps patients achieve A1C targets, with the added benefits of weight loss and no major hypoglycemia, could provide patients with an important option to improve their diabetes care."

"Together with our collaboration partners Lilly and Alkermes, we are pleased that exenatide once weekly met the primary endpoint of this superiority study and showed greater reduction in A1C than sitagliptin or pioglitazone. Additionally, from an average baseline of 193 pounds, at the end of the study patients on exenatide once weekly weighed an average of 14 pounds less than patients on pioglitazone and 4 pounds less than patients on sitagliptin," stated Orville G. Kolterman, M.D., senior vice president of research and development at Amylin Pharmaceuticals. "These data continue to build the value proposition for a once-weekly treatment that, if approved, has the potential to help patients improve their diabetes management."

"The results of this study provide us with more insight into the potential profile that may be achieved with exenatide once weekly," said Dr. Jim Malone, global medical director for exenatide, Eli Lilly and Company. "As we continue to progress through the series of DURATION studies, our goal is to clearly understand how exenatide once weekly compares to other diabetes therapies and be able to articulate, through the data, these differences to patients and their healthcare providers."

Over 80% of patients completed the study, and there was one withdrawal due to nausea in each treatment arm. There was no major hypoglycemia in any treatment group. The most frequently reported adverse events among exenatide once weekly and sitagliptin users were nausea and diarrhea. Upper respiratory tract infection and peripheral edema were the most frequently reported events by patients receiving pioglitazone.

Study Design

The 26-week double-blind, superiority study included 491 subjects with type 2 diabetes who were not achieving adequate glucose control using metformin therapy. There was no lead-in or wash-out period. The primary endpoint was reduction in A1C, while secondary endpoints included change in body weight along with other parameters of glucose control, cardiovascular health and patient-reported outcomes. Subjects were randomized to receive exenatide once weekly 2 milligrams by subcutaneous injection weekly, sitagliptin 100 milligrams daily, or pioglitazone 45 milligrams daily. Subjects in all treatment groups who completed the randomized portion of the study are continuing in an open-ended portion of the study receiving exenatide once weekly.

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 United States 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 United States and costs 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 support 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 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, 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-2 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, including the NDA filing for exenatide once weekly, not being submitted in a timely manner; regulatory approval 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 March 28, 2009.

(ii) The International Diabetes Federation Diabetes Atlas. Available at: http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A. Accessed March 28, 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 March 28, 2009.

(iv) Saydah SH, Fradkin J and 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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