Exenatide Once Weekly Provided Superior Glucose Control Compared to BYETTA® in DURATION-5 Study

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SAN DIEGO & INDIANAPOLIS & CAMBRIDGE, Mass., Dec 15, 2009 (BUSINESS WIRE) -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced positive results from a head-to-head study comparing exenatide once weekly, an investigational diabetes therapy, to BYETTA® (exenatide)injection taken twice daily, in patients with type 2 diabetes. After 24 weeks of treatment, patients taking exenatide once weekly experienced a statistically superior reduction in A1C, a measure of average blood sugar over three months, of 1.6 percentage points from baseline, compared to a reduction of 0.9 percentage points for BYETTA. Patients treated with exenatide once weekly achieved a mean A1C of 7.1 percent compared with a mean A1C of 7.7 percent in those treated with BYETTA. Both treatment groups achieved statistically significant weight loss by the end of the study, with an average loss of 5.1 pounds for patients taking exenatide once weekly and 3.0 pounds for patients taking BYETTA.

These findings are consistent with the results of other studies of exenatide once weekly and BYETTA. The companies conducted DURATION-5 to support regulatory submissions outside of the U.S. and provide additional controlled clinical data on the commercially manufactured product. DURATION is a series of clinical trials designed to test the superiority of exenatide once weekly as compared to currently available type 2 diabetes medications.

"The DURATION-5 data reinforce the efficacy of BYETTA and potential of exenatide once weekly in improving blood glucose control as measured by A1C, and build upon other successful DURATION trials," said Orville G. Kolterman, M.D., senior vice president of research and development, Amylin Pharmaceuticals. "More importantly, these results continue to suggest that if approved, exenatide once weekly could play an important role in advancing the treatment of type 2 diabetes by providing patients the opportunity for improved A1C control and weight loss with just one dose per week."

Approximately 80 percent of patients completed the study. Consistent with previous DURATION trials, the most frequently reported adverse event in both groups was nausea, reported less frequently by exenatide once weekly users (14 percent) than by BYETTA users (35 percent). There were no major hypoglycemic events. Cases of minor hypoglycemia in both groups were limited to patients using background sulfonylurea therapy.

The 24-week, open-label superiority study included approximately 250 participants with type 2 diabetes who were not achieving adequate glucose control using background therapies that included diet and exercise, metformin, sulfonylurea, thiazolidinediones or a combination of the agents. Patients were randomized to receive either exenatide once weekly or BYETTA. Patients in the exenatide once weekly treatment arm received 2 milligrams once a week, while patients in the BYETTA arm received 5 micrograms twice a day for the first four weeks and 10 micrograms twice a day for the remaining 20 weeks. The primary endpoint was reduction in A1C; secondary endpoints included change in body weight and fasting plasma glucose, safety and tolerability.

Amylin, Lilly and Alkermes submitted a new drug application (NDA) for exenatide once weekly to the U.S. Food and Drug Administration (FDA) in May 2009; the NDA was accepted for review in July 2009. Lilly will be responsible for marketing exenatide once weekly outside the U.S. and expects to submit a marketing application to the European Medicines Agency by the end of the second quarter in 2010.

About Diabetes

Diabetes affects more than 24 million people in the U.S., and it is estimated that by 2010,it will affect 284.6 million adults worldwide.[1,2] 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 costs approximately $174 billion per year in direct and indirect medical expenses.[3]

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.[4] In addition, 85 percent of type 2 diabetes patients are overweight and 55 percent are considered obese.[5] Data indicate that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.[6,7]

About BYETTA® (exenatide) injection

BYETTA is the first and only FDA-approved GLP-1 receptor agonist 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 improves blood sugar after food intake through multiple effects that work in concert on the stomach, liver, pancreas and brain.

BYETTA is an injectable prescription medicine that may improve blood sugar (glucose) control in adults with type 2 diabetes mellitus, when used with a diet and exercise program. BYETTA is not insulin and should not be taken instead of insulin. BYETTA is not recommended to be taken with insulin. BYETTA is not for people with type 1 diabetes or people with diabetic ketoacidosis.

BYETTA provides sustained A1C control and low incidence of hypoglycemia when used alone or in combination with metformin or a thiazolidinedione, with potential weight loss. BYETTA is not a weight loss product. BYETTA was approved in April 2005 and has been used by more than one million patients since its introduction. For full prescribing information, visit http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.BYETTA.com&esheet=6120725&lan=en_US&anchor=www.BYETTA.com&index=1&md5=0d7787200688c590e384abc592d3c33c.

Important Safety Information for BYETTA® (exenatide) injection

Based on post-marketing data, BYETTA has been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. The risk for getting low blood sugar is higher if BYETTA is taken with another medicine that can cause low blood sugar, such as a sulfonylurea. BYETTA should not be used in people who have severe kidney problems, and should be used with caution in people who have had a kidney transplant. Patients should talk with their healthcare provider if they have severe problems with their stomach, such as delayed emptying of the stomach (gastroparesis) or problems with digesting food. Severe allergic reactions can happen with BYETTA.

The most common side effects with BYETTA include nausea, vomiting, diarrhea, dizziness, headache, feeling jittery, and acid stomach. Nausea most commonly happens when first starting BYETTA, but may become less over time.

These are not all the side effects from use of BYETTA. A healthcare provider should be consulted about any side effect that is bothersome or does not go away.

For Prescribing Information and Medication Guide, visit www.BYETTA.com.

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 Medisorb® technology for long-acting medications. Exenatide once weekly is not currently approved by any regulatory agencies.

Amylin Pharmaceuticals is a biopharmaceutical company dedicated to improving lives of patients 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 not confirming previous results, or not achieving the intended clinical endpoints; the DURATION-5 superiority study results potentially not being predictive of real world use; 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 of 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.

[1] The International Diabetes Federation Diabetes Atlas. Available at: http://www.diabetesatlas.org/content/regional-overview. Accessed on Dec. 14, 2009.

[2] Diabetes Statistics. American Diabetes Association. Available at http://www.diabetes.org/diabetes-basics/diabetes-statistics/. Accessed Dec. 14, 2009.

[3] Direct and Indirect Costs of Diabetes in the United States. American Diabetes Association. Available at: http://www.diabetes.org/how-to-help/action/resources/cost-of-diabetes.html. Accessed Dec. 14, 2009.

[4] Saydah SH, Fradkin J and Cowie CC. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. *JAMA*. 2004;291:335-42.

[5] 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.

[6] Nutrition Recommendations and Interventions for Diabetes: a position statement of the American Diabetes Association. *Diabetes Care*. 2007;30 Suppl 1:S48-65. [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.

SOURCE: Alkermes, Inc. & Amylin Pharmaceuticals, Inc. & Eli Lilly and Company

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