After One Year, Type 2 Diabetes Patients Taking Exenatide Once Weekly Sustained Improvements in Glycemic Control and Weight; DURATION-1 Presented at ADA 2008

June 9, 2008

Phase 3 Once Weekly Investigational Diabetes Therapy Also Improved Glucose Control in Patients Switching from Exenatide Taken Twice a Day

SAN FRANCISCO, June 9, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY), and Alkermes, Inc. (Nasdaq: ALKS) today announced results from a 52-week open-label clinical study that showed the durable efficacy of exenatide once weekly, a long-acting release formulation of exenatide. Patients taking exenatide once weekly over the course of one year sustained a similar improvement in glucose control [A1C: -2.0%+/-0.08; fasting plasma glucose (FPG) -47+/-3 mg/dL] compared to those receiving treatment for 30 weeks [A1C change from baseline: -1.9%+/-0.08 (LS mean+/-SE)]. This study also showed that patients who switched from BYETTA® (exenatide) injection after 30 weeks to exenatide once weekly experienced additional improvements in A1C and fasting plasma glucose. Seventy-four percent of all patients in the study achieved an endpoint A1C of 7 percent or less at 52 weeks. Patients in both treatment groups experienced a statistically significant and sustained average weight loss of 9.5 pounds over 52 weeks. These findings were presented at the 68th Annual Scientific Sessions of the American Diabetes Association (ADA) in San Francisco.

BYETTA is indicated as adjunctive therapy to improve glycemic control in patients with type 2 diabetes mellitus who are taking metformin, a sulfonylurea, a thiazolidinedione, a combination of metformin and a sulfonylurea, or a combination of metformin and a thiazolidinedione, but have not achieved adequate glycemic control.

"Diabetes is a lifelong condition that requires constant management of blood glucose or blood sugar as well as weight. In DURATION-1 trial, patients significantly reduced their blood glucose levels and, on average, lost a total of over nine pounds. These improvements were sustained for a year," said John B. Buse, M.D., Ph.D., Professor of Medicine, Director of the Diabetes Care Center, and Chief of the Division of Endocrinology at the University of North Carolina School of Medicine in Chapel Hill. "Importantly, the study results also showed that steady-state levels of exenatide may result in improvements in a variety of glucose parameters. If approved, exenatide once weekly may provide patients with a treatment option that is on board 24 hours a day, seven days a week, helping to manage their blood sugar and, secondarily, their weight."

Study Design and Findings

The Diabetes Therapy Utilization: Researching Changes in A1C, Weight and Other Factors Through Intervention with Exenatide ONce Weekly (DURATION-1) study was a 30-week, randomized, open-label study of 295 patients with type 2 diabetes (baseline values: A1C 8.3%+/-1.0, FPG 169+/-43 mg/dL, weight 225+/-44lbs., BMI 35+/-5.0 kg/m2, diabetes duration 6.7+/-5.0 years; mean+/-SD) who were treated with exenatide once weekly 2.0 mg or BYETTA twice daily as outlined in the approved label subcutaneously. Following the first 30 weeks of treatment, 258 patients entered an open-label treatment with exenatide once weekly. Patients either remained on exenatide once weekly or switched from BYETTA to exenatide once weekly for an additional 22 weeks.

Following the 30-week comparison period, patients (evaluable population N=241) who continued on exenatide once weekly showed sustained improvements in A1C and fasting plasma glucose levels at week 52 [A1C: -2.0%+/-0.1; FPG -47+/-3 mg/dL (LS mean+/-SE)]. Patients who switched from BYETTA to exenatide once weekly had further improvements in glycemic control [A1C: -2.0% +/-0.1; FPG - 43+/-3 mg/dL] that were consistent with those of patients receiving exenatide once weekly for 52 weeks. These data suggested the additional impact of continuous exenatide levels on glycemic control.

In both groups, A1C reduction was similar at 52 weeks. Seventy-two percent of patients treated with exenatide once weekly achieved an endpoint A1C of 7 percent or less, and 54 percent achieved an A1C of 6.5 percent or less. In patients who switched from BYETTA to exenatide once weekly, 75 percent of patients achieved an endpoint A1C of 7 percent or less and 53 percent achieved an A1C of 6.5 percent or less. An A1C of below 7 percent is the target for good glucose control as recommended by the ADA. Unlike the weight gain that is commonly associated with insulin therapy and many oral diabetes medications, exenatide once weekly was associated with an average weight loss of 9.5 pounds over 52 weeks.

Exenatide once weekly uses a proprietary technology for long-acting medications 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 in a controlled manner to provide continuous therapeutic exenatide levels in plasma.

Safety Profile

Exenatide once weekly was well tolerated during the first 30 weeks of treatment and the following 22-week, open-ended treatment period with overall tolerability improving over the course of the study. No major hypoglycemia events regardless of background therapy, were observed with exenatide once weekly. Cases of minor hypoglycemia with exenatide once weekly and with BYETTA use were limited to patients using background sulfonylurea therapy. In both groups, nausea was predominantly mild and transient and occurred less frequently in exenatide once weekly patients. Patients switching from BYETTA to exenatide once weekly did not experience a significant increase in nausea following the transition. The antibody profiles of patients treated in this study were consistent with the previously reported profiles of BYETTA and exenatide once weekly. These data further supported the known safety profile of the exenatide molecule.

About BYETTA® (exenatide) injection

BYETTA is the first and only FDA-approved incretin mimetic 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 approved by the FDA for use by people with type 2 diabetes who are unsuccessful at controlling their blood sugar levels. BYETTA is an add-on therapy for people currently using metformin, a sulfonylurea, or a thiazolidinedione. BYETTA provides sustained A1C control, low incidence of hypoglycemia when used with metformin or a thiazolidinedione, and progressive weight loss. BYETTA was approved in April 2005 and has been used by approximately one million patients since its introduction. For full prescribing information, visit www.BYETTA.com.

About Diabetes

Diabetes affects more than 21 million in the United States and an estimated 246 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 United States and costs approximately $132 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 support that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.(6)(7)

Important Safety Information for BYETTA

BYETTA improves glucose (blood sugar) control in adults with type 2 diabetes. It is used with metformin, a sulfonylurea, or a thiazolidinedione. 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.

When BYETTA is used with a medicine that contains a sulfonylurea, hypoglycemia (low blood sugar) 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 the most common side effect when first starting BYETTA, but decreases over time in most patients.

If patients experience the following severe and persistent symptoms (alone or in combination): abdominal pain, nausea, vomiting, or diarrhea, they should talk to their healthcare provider because these symptoms could be signs of serious medical conditions. 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 of 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 full prescribing information, 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 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 has developed and gained approval for two first-in-class medicines for diabetes, SYMLIN® (pramlintide acetate) injection and BYETTA® (exenatide) injection. 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 with over 2,000 employees nationwide. Further information about Amylin Pharmaceuticals 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 healthcare 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, Indiana, 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., a biotechnology company committed to developing innovative medicines to improve patients' lives, manufactures RISPERDAL® CONSTA® for schizophrenia and developed and manufactures VIVITROL® for alcohol dependence. 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 and manufacturing facilities in Massachusetts and Ohio.

This press release contains forward-looking statements about Amylin, Lilly and Alkermes. 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 BYETTA and the revenues generated from BYETTA may be affected by competition; unexpected new data; technical issues; clinical trials not confirming previous results; pre-clinical trials not predicting future results; new drug applications and label expansion requests not being submitted in a timely manner or receiving regulatory approval; or manufacturing and supply issues. The potential for BYETTA 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 commercialization of pharmaceutical products. These and additional risks and uncertainties are described more fully in the companies' most recently filed SEC documents including their Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K. The companies undertake no duty to update these forward-looking statements.

(1) The International Diabetes Federation Diabetes Atlas. Available at: http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A. Accessed June 2, 2008.

(2) "All About Diabetes." American Diabetes Association. Available at: http://www.diabetes.org/about-diabetes.jsp. Accessed June 2, 2008.

(3) "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 June 2, 2008.

(4) 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.

(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.

(7) 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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(Logo: http://www.newscom.com/cgi-bin/prnh/20060610/AMYLINLOGO)

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