Exenatide Once Weekly Provided Sustained Improvements in Glycemic Control with Weight Loss Over Two Years: DURATION-1 Interim Long-Term Data Presented at ADA 2009

June 7, 2009

Improvements in Systolic Blood Pressure and Triglycerides Also Observed

NEW ORLEANS--(BUSINESS WIRE)--Jun. 7, 2009-- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY), and Alkermes, Inc. (Nasdaq: ALKS) today announced long-term, interim results from the DURATION-1 study that showed sustained glucose control with weight loss, as well as improvements in systolic blood pressure and triglycerides, through two years of treatment with exenatide once weekly, an investigational therapy for type 2 diabetes. These findings were presented at the 69th Annual Scientific Sessions of the American Diabetes Association (ADA) in New Orleans. A New Drug Application (NDA) for exenatide once weekly was recently submitted to the U.S. Food and Drug Administration.

In the controlled portion of the open-label study, patients received exenatide once weekly or BYETTA® (exenatide) injection for 30 weeks, followed by 74 weeks of treatment with exenatide once weekly for all patients during an open-ended assessment period. Significant reductions in A1C of 1.7 percent and fasting plasma glucose (FPG) of 40 mg/dL were maintained after two years of treatment. Sixty-five percent of patients achieved an A1C of 7 percent or less. (A1C of less than 7 percent is the target for good glucose control as recommended by the ADA.) Body weight was significantly reduced, with patients losing an average of 5.8 pounds. Serum lipid profiles were significantly improved, and there was a significant reduction in systolic blood pressure (SBP).

“These two-year DURATION-1 data showed that maintenance of steady state concentrations of exenatide may result in sustained improvements in glycemic control, with potential weight loss,” said Orville G. Kolterman, M.D., senior vice president of research and development at Amylin. “In DURATION-1, exenatide once weekly has been shown to provide superior glycemic control, with weight loss, compared to BYETTA. If approved, this therapy could fill an important unmet need for treating patients with type 2 diabetes with just one dose per week.”

Study Design and Findings

The study enrolled 295 patients, with nearly 75 percent completing the two years of treatment. Baseline characteristics for these patients were: A1C 8.2±1.0%, FPG 168±43 mg/dL, body weight 223±41 pounds, BMI 34.8±4.8 kg/m^2, diabetes duration 7.1±5.3 years. Significant improvements in both A1C [-1.7±0.1%] and FPG [-40±3 mg/dL] were maintained after two years of treatment, body weight was significantly reduced [-5.8±1.2 pounds], serum lipid profiles were significantly improved [total cholesterol -8.6±2.8 mg/dL; LDL cholesterol -4.5±2.2 mg/dL; triglycerides -15±3 percent], and there was a significant reduction in SBP [-3.0±1.0 mmHg for all participants and -9.4±1.5 mmHg for those with abnormal baselines].

Safety Profile

Nausea was the most common event during the 30-week treatment period and decreased over time, occurring in 12 percent of patients during the 74-week assessment period when all patients were receiving exenatide once weekly. No severe hypoglycemia was observed. The safety profile of patients treated in this study was consistent with the previously reported profiles of BYETTA and exenatide once weekly.

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 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 support that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.(vi,vii)

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 and low incidence of hypoglycemia when used 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 1 million patients since its introduction. For full prescribing information, visit www.BYETTA.com.

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'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 BYETTA, exenatide once weekly, and/or the revenues generated from BYETTA and/or exenatide once weekly may be affected by competition; unexpected new data; safety and technical issues; pre-clinical trial results; 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-1 study extension results potentially not being accepted to support comparability; label expansion requests or NDA filings, including the NDA filing mentioned in this press release, not being submitted and/or accepted in a timely manner; regulatory approval being delayed or not received; or manufacturing and supply issues. The potential for BYETTA and/or 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.

P-LLY

(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.

Source: Alkermes, Inc.

Amylin
Anne Erickson, 858-754-4443
Cell: 858-349-3195
anne.erickson@amylin.com
or
Lilly
Kindra Strupp, 317-277-5170

Cell: 317-554-9577
kstrupp@lilly.com
or
Alkermes
Rebecca Peterson, 617-583-6378
Cell: 617-899-2447
rebecca.peterson@alkermes.com