Plans for Exenatide Once Weekly NDA Submission by End of First Half of 2009 Reaffirmed Following FDA Feedback

December 11, 2008

Companies Intend To Use Ongoing Study To Meet Manufacturing Comparability Requirements

SAN DIEGO, INDIANAPOLIS, and CAMBRIDGE, Mass., Dec 11, 2008 /PRNewswire via COMTEX News Network/ -- Amylin Pharmaceuticals, Inc., (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced that the U.S. Food and Drug Administration (FDA) recently indicated that the ongoing extension of the DURATION-1 study is appropriate to use as the basis for demonstrating comparability between intermediate-scale clinical trial material made in Alkermes' manufacturing facility, and commercial-scale drug product made at Amylin's manufacturing facility.

"Following feedback from FDA, we now have an appropriate pathway to demonstrate manufacturing comparability of exenatide once weekly. This is a very important step for the submission of exenatide once weekly," said Orville G. Kolterman, M.D., senior vice president, research and development at Amylin Pharmaceuticals. "We remain confident that our NDA submission is on track to be completed by the end of the first half of 2009."

Final acceptance of the comparability data is dependent upon DURATION-1 study extension results that are expected in early 2009.

DURATION Program Update

The overall DURATION clinical program, designed to demonstrate superiority of exenatide once weekly as compared to other medications in the treatment of type 2 diabetes, remains on track. The companies recently initiated DURATION-4, the fourth planned DURATION study. The DURATION-4 study examines exenatide once weekly as a monotherapy treatment compared to either metformin, a thiazolidinedione (TZD) or a dipeptidyl peptidase-4 (DPP-4) inhibitor. The double-blind study is expected to include approximately 800 patients and complete in 2010.

"We are confident that the strategy of the DURATION program will yield powerful data to support a strong launch for exenatide once weekly," said James Malone, M.D., global exenatide medical director, Eli Lilly and Company. "We believe the program will demonstrate the value of exenatide once weekly to physicians, patients and payers."

DURATION-3 completed enrollment in the fourth quarter. This approximately 450 patient, open-label, superiority study compares exenatide once weekly with insulin glargine on a background of oral agent therapy. Results are expected in the third quarter of 2009.

DURATION-2 completed enrollment in the third quarter of 2008. This 500 patient, double-blind, superiority study compares exenatide once weekly with TZD and a DPP-4 inhibitor on a background of metformin therapy. Results are expected in the second quarter of 2009.

DURATION is an acronym for the overall exenatide once weekly clinical program. It stands for "Diabetes therapy Utilization: Researching changes in A1C, weight and other factors Through Intervention with exenatide ONce weekly."

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.

About Diabetes

Diabetes affects more than 23 million 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 $132 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(R) (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.

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 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. 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/or exenatide once weekly and the revenues generated from BYETTA may be affected by competition; unexpected new data; safety and technical issues; clinical trials, including the clinical trials 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; pre-clinical trials not predicting future results; label expansion requests or NDA filings, including the NDA filing mentioned in this press release, not being submitted 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.

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

(ii) "All About Diabetes." American Diabetes Association. Available at: http://www.diabetes.org/about-diabetes.jsp. Accessed June 8, 2008.

(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 June 8, 2008.

(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. 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 Eli Lilly and Company