Exenatide Once Weekly New Drug Application Submitted to FDA for Type 2 Diabetes

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SAN DIEGO, Calif., INDIANAPOLIS, Ind., and CAMBRIDGE, Mass. – May 5, 2009 – Amylin Pharmaceuticals, Inc., (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced that a New Drug Application (NDA) for exenatide once weekly has been submitted to the U.S. Food and Drug Administration (FDA). Exenatide once weekly is an investigational sustained release medication for type 2 diabetes that is injected subcutaneously and administered only once a week. Exenatide is the active ingredient in BYETTA® (exenatide) injection, which is currently available in the U.S. and in many countries worldwide for people with type 2 diabetes who are unable to achieve good glycemic control with common oral therapies.

"The exenatide once weekly submission is an important milestone in the overall exenatide development program. The clinical data supporting this submission highlight the potential of exenatide once weekly to significantly advance the treatment of type 2 diabetes," said Daniel M. Bradbury, president and chief executive officer of Amylin. "We remain committed to developing and commercializing a range of treatment options that address the important unmet needs of people living with diabetes."

Clinical components of the NDA include the DURATION-1 study and the meta-analysis of primary cardiovascular events across the BYETTA clinical database. DURATION-1 was designed to test the superiority of exenatide once weekly, as compared to BYETTA, which is administered twice daily. In this study, exenatide once weekly treatment resulted in statistically significant reductions in A1C of 1.9 percentage points from baseline, compared to a reduction of 1.5 percentage points for BYETTA, and 77 percent of patients treated with exenatide once weekly achieved an A1C of 7 percent or less compared to 61 percent of patients treated with BYETTA. Exenatide once weekly and BYETTA were both associated with an average weight loss of 8 pounds from baseline. The most commonly reported adverse event was nausea, which was typically mild and transient and occurred less frequently in the exenatide once weekly patients. In addition, a meta-analysis across controlled clinical studies of three months or greater from the BYETTA database showed no increased risk of cardiovascular events associated with exenatide use. This analysis applied principles outlined in the FDA's guidance for evaluating cardiovascular risk in type 2 diabetes agents.

Components of the submission supporting product manufacturing include analyses to demonstrate comparability of the intended commercial product with that used during development. These analyses include data from patients in the ongoing extension of the DURATION-1 study who used exenatide once weekly produced at Amylin's manufacturing facility in Ohio.

"If approved, exenatide once weekly would be the first and only once-a-week therapy for the treatment of type 2 diabetes," said David Vondle, exenatide global brand development leader for Lilly. "A new treatment option to help patients with type 2 diabetes manage blood sugar, with potential weight loss and less frequent dosing, could offer an important advance in the treatment paradigm for patients and physicians who manage this chronic condition."

About Diabetes
Diabetes affects more than 23 million people in the U.S. 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 U.S. 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 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 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 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 and/or the approval of exenatide once weekly and 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 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; 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.

(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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