Amylin, Lilly and Alkermes Submit Reply to FDA Complete Response Letter for BYDUREON™

April 22, 2010

Classification of Submission and New PDUFA Action Date Expected Within 14 Days, per FDA Guidelines

SAN DIEGO, INDIANAPOLIS & WALTHAM, Mass., Apr 22, 2010 (BUSINESS WIRE) --Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced that the companies have submitted their reply to a complete response letter issued last month by the U.S. Food and Drug Administration (FDA) after review of the New Drug Application (NDA) submission for BYDUREON™ (exenatide for extended-release injectable suspension). In accordance with its guidelines, the FDA is expected to classify the complete response as a Class 1 or Class 2 resubmission, and also provide the companies with an updated Prescription Drug User Fee Act (PDUFA) target action date within the next two weeks.

The companies' reply addresses requests from the FDA primarily related to finalization of the product labeling with accompanying Risk Evaluation and Mitigation Strategy (REMS) and clarification of existing manufacturing processes.

The FDA's complete response letter did not request new pre-clinical or clinical trials, nor did it contain requests related to the December 2009 observations from the FDA's pre-approval inspection at the Ohio manufacturing facility. All of these observations have been addressed.

"The companies have worked diligently and quickly over the last few weeks to submit a complete response and are confident we addressed the requests that were outlined by the FDA," said Orville G. Kolterman, M.D., senior vice president of research and development, Amylin Pharmaceuticals. "We are committed to making BYDUREON available to patients as soon as possible and will continue to work closely with the agency toward our goal."

BYDUREON (pronounced by-DUR-ee-on) is the proposed brand name for exenatide once weekly. It is an investigational, extended-release medication for type 2 diabetes designed to deliver continuous therapeutic levels of exenatide in a single weekly dose. BYDUREON is a once-weekly formulation of exenatide, the active ingredient in BYETTA® (exenatide) injection, which has been available in the U.S. since June 2005 and is used in approximately 60 countries worldwide to improve glycemic control in adults with type 2 diabetes. BYDUREON and BYETTA belong to the glucagon-like peptide-1 (GLP-1) receptor agonist class of medications.

The NDA for BYDUREON was submitted in May 2009 and was based on data from the DURATION clinical trial program, as well as more than seven years of clinical experience with BYETTA. The NDA was accepted by the FDA in July 2009. The agency issued a complete response letter to the companies in March 2010.

About Diabetes

Diabetes affects more than 24 million people in the U.S. and an estimated 285 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 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. See important safety information below. Additional information about BYETTA is at http://www.byetta.com/Pages/index.aspx.

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 additional important safety information about BYETTA, please see the full Prescribing Information (http://pi.lilly.com/us/byetta-pi.pdf) and Medication Guide (http://pi.lilly.com/us/byetta-ppi.pdf).

About Amylin, Lilly and Alkermes

Amylin, Lilly and Alkermes are working together to develop BYDUREON, a subcutaneous injection of exenatide for the treatment of type 2 diabetes based on Alkermes' proprietary Medisorb®technology for long-acting medications. BYDUREON 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 Waltham, Massachusetts, Alkermes has a research facility 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 BYDUREON may not be approved by the FDA in a timely manner or at all; the information provided in the companies' response to the FDA's complete response letter may not satisfy the FDA; the FDA may request additional information prior to approval; BYETTA and/or the approval of BYDUREON and the revenues generated from these products may be affected by competition; unexpected new data; safety and technical issues; clinical trials not being completed in a timely manner, not confirming previous results, not being predictive of real world use or not achieving the intended clinical endpoints; label expansion requests or NDA filings, such as the NDA filing for BYDUREON mentioned in this press release, not receiving regulatory approval; the commercial launch of BYDUREON, if approved, being delayed; or manufacturing and supply issues. The potential for BYETTA and/or BYDUREON 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/some-285-million-people-worldwide-will-live-diabetes-2010. Accessed April 4, 2010.

[2] Diabetes Statistics. American Diabetes Association. Available at http://www.diabetes.org/diabetes-basics/diabetes-statistics/. Accessed April 4, 2010.

[3] Direct and Indirect Costs of Diabetes in the United States. American Diabetes Association. Available at: http://www.diabetes.org/how-to-give/action/resources/cost-of-diabetes.html. Accessed April 4, 2010.

[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.

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