BYDUREON™ Receives Marketing Authorization in Europe

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First and Only Once-Weekly Type 2 Diabetes Medication Delivers Powerful Glycemic Control in a Single Dose

INDIANAPOLIS, SAN DIEGO & WALTHAM, Mass., Jun 21, 2011 (BUSINESS WIRE) -- Eli Lilly and Company (NYSE: LLY), together with Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) and Alkermes, Inc. (Nasdaq: ALKS), announced today that the European Commission has granted marketing authorization to BYDUREON™(exenatide 2 mg powder and solvent for prolonged release suspension for injection).

BYDUREON, a glucagon-like peptide-1 (GLP-1) receptor agonist, is the first once-weekly treatment for type 2 diabetes. It delivers glycemic control in a single weekly dose and is indicated for the treatment of type 2 diabetes in adult patients in combination with metformin, a sulfonylurea, a thiazolidinedione, metformin plus a sulfonylurea or metformin plus a thiazolidinedione.

"As the global impact of diabetes continues to expand, so does the need for innovative medicines to help people living with diabetes successfully fit treatment into their lives," said Enrique Conterno, president, Lilly Diabetes. "BYDUREON is the first and only once-weekly treatment for type 2 diabetes and has demonstrated powerful efficacy in multiple clinical trials."

The EU Marketing Authorization of BYDUREON is based on review of the submission package, including data from studies in the DURATION clinical program in which exenatide resulted in improvements in glycemic control with just one dose per week. In the data submitted, BYDUREON showed statistically significant improvements in glycemic control based on reduction of A1C (a measure of average blood sugar over three months) between 1.5 and 1.9 percent after six months. Although BYDUREON was not studied as a weight-loss product, most patients taking BYDUREON lost weight. Further, the BYDUREON submission builds upon six years of market experience with BYETTA® (exenatide) injection, the twice-daily form of exenatide that is available in more than 70 countries worldwide. The most common side effect with BYDUREON in clinical trials was mild-to-moderate nausea, which affected approximately 20 percent of patients and decreased over time in most patients. Other common side effects were vomiting, diarrhea and constipation.

In the U.S., the New Drug Application for BYDUREON (exenatide extended-release for injectable suspension) was submitted to the U.S. Food and Drug Administration (FDA) in 2009. The FDA issued a complete response letter and requested further data in late 2010. The companies plan to submit a response in the second half of 2011. BYDUREON is the proposed trade name.

BYDUREON is delivered using a biodegradable microsphere technology developed by Alkermes. The medicine offers a continuous release of exenatide with just one weekly dose.

About Diabetes

Diabetes affects an estimated 285 million adults worldwide and nearly 26 million people in the U.S.[1,2] Approximately 90-95 percent of those affected have type 2 diabetes. Diabetes costs exceed $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 was the first glucagon-like peptide-1 (GLP-1) receptor agonist to be approved by the FDA for the treatment of type 2 diabetes. BYETTA exhibits many of the same effects as the human incretin hormone 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 currently recommended to be taken with insulin. BYETTA is not for people with type 1 diabetes or people with diabetic ketoacidosis. BYETTA has not been studied in people who have pancreatitis.

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 the U.S. in April 2005 and in Europe in November 2006 and has been used by more than 1.8 million patients since its introduction. See important safety information below. Additional information about BYETTA is available at http://www.byetta.com/.

Important Safety Information for BYETTA® (exenatide) injection

Based on postmarketing data BYETTA has been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. Patients should be observed for signs and symptoms of pancreatitis after initiation or dose escalation of BYETTA. 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. Antibodies may develop with use of BYETTA. Patients who develop high titers to exenatide could have worsening or failure to achieve adequate glycemic control. Consider alternative therapy if this occurs. Severe allergic reactions can happen with BYETTA. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with BYETTA or any other antidiabetic drug.

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 (www.byetta.com/pi) and Medication Guide (www.byetta.com/mg).

About Amylin, Lilly and Alkermes

Amylin and Lilly partnered to develop and market BYDUREON, which is based on proprietary technology for long-acting medications developed by Alkermes, Inc. BYDUREON was approved in the EU in June 2011 and is under regulatory review in the U.S.

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.

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, 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 and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Waltham, Mass., 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 as soon as anticipated or at all; the companies' response to the FDA's complete response letter may not be submitted in a timely manner and/or the information provided in such response 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 not receiving regulatory approval; the commercial launch of BYDUREON 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] Diabetes Statistics. American Diabetes Association. Available at www.diabetes.org/diabetes-basics/diabetes-statistics. Accessed June 14, 2011.

[2] The International Diabetes Federation Diabetes Atlas. Available at: www.diabetesatlas.org/content/some-285-million-people-worldwide-will-live-diabetes-2010. Accessed June 14, 2011.

[3] Direct and Indirect Costs of Diabetes in the United States. American Diabetes Association. Available at: www.diabetes.org/how-to-help/action/resources/cost-of-diabetes.html. Accessed June 14, 2011.

[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* 2008; 31 Suppl 1; S61-78. [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.

SOURCE: Alkermes, Inc.

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