



Amylin and Lilly Seek Expanded Use of BYETTA® Along with Basal Insulin

SAN DIEGO and INDIANAPOLIS, Dec. 22, 2010 /PRNewswire/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) and Eli Lilly and Company (NYSE: LLY) today announced that a supplemental New Drug Application (sNDA) has been submitted to the U.S. Food and Drug Administration (FDA) for the expanded use of BYETTA® (exenatide) injection as an add-on therapy to basal insulin, with or without metformin and/or a thiazolidinedione (TZD) in conjunction with diet and exercise for adults with type 2 diabetes who are not achieving adequate glycemic control.

BYETTA, the first marketed GLP-1 receptor agonist, was approved in the U.S. in April 2005 for the treatment of type 2 diabetes as add-on therapy to diet and exercise for adult patients not achieving adequate glycemic control using commonly prescribed oral diabetes medications. In October 2009, BYETTA was approved as monotherapy along with diet and exercise. BYETTA is available in more than 60 countries worldwide.

"Many patients using basal insulin with or without oral diabetes medications are unable to maintain adequate blood sugar control, particularly at mealtime," said Orville G. Kolterman, M.D., senior vice president, chief medical officer, Amylin Pharmaceuticals. "If approved for this expanded use, BYETTA may provide a complementary addition to basal insulin to improve overall blood sugar control with no weight gain and no increased risk of hypoglycemia. The combination may also offer a mealtime treatment option that is taken only twice a day and does not require dosing titration."

The sNDA is based on a double-blind, placebo-controlled clinical study evaluating BYETTA added to Lantus® (insulin glargine). The study showed many hard-to-treat patients with type 2 diabetes who were poorly controlled on basal insulin therapy with or without metformin and/or a TZD achieved A1C control without weight gain or increasing their risk of hypoglycemia. A total of 261 patients receiving insulin glargine, with or without oral agents, were randomized to receive BYETTA or placebo in addition to aggressive insulin titration. After 30 weeks of treatment, A1C on average decreased by 1.7 percentage points in patients adding BYETTA, compared with a decrease of 1.0 percentage point in patients treated with insulin alone. Both treatment groups showed lower fasting plasma glucose concentrations; however, after morning and evening meals, when BYETTA was administered, postprandial glucose control was significantly improved with BYETTA compared to placebo. On average, weight decreased by 4 pounds in patients adding BYETTA, compared with an increase of 2 pounds in patients treated with insulin alone. The greater improvement in A1C with BYETTA was not accompanied by an increase in hypoglycemia, compared to placebo.

Nausea was the most common adverse event during the 30-week treatment period and decreased over time. Nausea occurred in 41 percent of patients treated with BYETTA compared with 8 percent of patients treated with insulin alone. Hypoglycemia was similar for both groups; major hypoglycemia occurred twice in one patient receiving insulin alone.

The study was published in the Dec. 7, 2010 *Annals of Internal Medicine*.

About Diabetes

Diabetes affects more than 24 million people in the U.S. and an estimated 285 million adults worldwide.(i), (ii) Approximately 90-95 percent of those affected have type 2 diabetes. Diabetes 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 indicate 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 was 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 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 TZD, with potential weight loss (BYETTA is not a weight-loss product). BYETTA was approved in April 2005 and has been used by more than 1.3 million patients since its introduction. See important safety information below. Additional information about BYETTA is available at www.BYETTA.com.

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

About Amylin and Lilly

Amylin Pharmaceuticals is a biopharmaceutical company dedicated to improving lives of patients through the discovery, development and commercialization of innovative medicines. Amylin has developed and gained approval for two first-in-class medicines for diabetes, SYMLIN® (pramlintide acetate) injection and BYETTA® (exenatide) injection. 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. Further information on Amylin Pharmaceuticals is available at www.amylin.com.

Through a long-standing commitment to diabetes care, Lilly seeks to provide patients with breakthrough treatments that enable them to live longer, healthier and fuller lives. Since 1923, Lilly has been an 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. For more information about Lilly's current diabetes products, visit www.lillydiabetes.com.

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. Additional information about Lilly is available at www.lilly.com.

This press release contains forward-looking statements about Amylin and Lilly. 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 revenues generated from BYETTA, may be affected by competition; unexpected new data; safety and technical issues; clinical trials, including the trial mentioned in this press release, 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, including the request mentioned in this press release, not receiving regulatory approval; or manufacturing and supply issues. The potential for BYETTA 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 and/or Lilly. These and additional risks and uncertainties are described more fully in Amylin's and Lilly's most recent SEC filings, including their Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K. Amylin and Lilly undertake no duty to update these forward-looking statements.

BYETTA® is a registered trademark of Amylin Pharmaceuticals, Inc. All other marks are the marks of their respective owners.

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(i) The International Diabetes Federation Diabetes Atlas. Available at: <http://www.diabetesatlas.org/content/some-285-million-people-worldwide-will-live-diabetes-2010>. Accessed December 16, 2010.

(ii) Diabetes Statistics. American Diabetes Association. Available at <http://www.diabetes.org/diabetes-basics/diabetes-statistics/>. Accessed December 16, 2010.

(iii) Direct and Indirect Costs of Diabetes in the United States. American Diabetes Association. Available at: <http://www.diabetes.org/how-to-help/action/resources/cost-of-diabetes.html>. Accessed December 16, 2010.

(iv) 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.

(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.

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