



BYETTA® Approved for Use with Basal Insulin in Europe

Patients in Pivotal Study Achieved Better Glycemic Control Overall and After Meals

SAN DIEGO and INDIANAPOLIS, March 23, 2012 /PRNewswire/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) and Eli Lilly and Company (NYSE: LLY) announced today that the European Commission has granted marketing authorization to BYETTA® (exenatide twice-daily) as an adjunctive therapy to basal insulin, with or without metformin and/or Actos® (pioglitazone), for the treatment of type 2 diabetes in adults who have not achieved adequate glycemic control with these agents.

"The marketing authorization for the use of BYETTA with basal insulin provides a new option for the many patients with type 2 diabetes who are not achieving treatment goals," said Christian Weyer, M.D., senior vice president, research and development, Amylin Pharmaceuticals. "In a clinical trial, patients using fixed-dose BYETTA with titrated basal insulin achieved better postprandial and overall glycemic control, without weight gain or an increased risk of hypoglycemia, compared to patients using titrated basal insulin without BYETTA."

The main study included in the EU marketing authorization submission package was a double-blind, 30-week clinical trial published in *Annals of Internal Medicine*.⁽¹⁾ In the study, BYETTA 10 micrograms or placebo was added to existing insulin glargine therapy (with or without metformin, pioglitazone or both), which was titrated to achieve target fasting glucose levels. At study entry, patients who may have been at increased risk of hypoglycemia (A1C less than or equal to 8 percent) reduced their dose of insulin glargine by 20 percent. Five weeks after randomization, all patients had insulin doses titrated to achieve target fasting glucose levels. The primary endpoint was reduction in A1C, a measure of average blood sugar over three months; secondary endpoints included change in body weight along with other parameters of glucose control, cardiovascular health, hypoglycemia and patient-reported outcomes.

After 30 weeks of treatment, BYETTA demonstrated a statistically significant reduction in A1C compared to placebo, lowering A1C by 1.7 percentage points from a baseline of 8.3 percent. Patients treated with optimized insulin glargine plus placebo experienced a 1.0 percentage point decrease in A1C from a baseline of 8.5 percent. Patients who added BYETTA to their insulin glargine regimen saw their weight decrease by an average of 4 pounds, compared with an increase of 2 pounds in patients who were treated with optimized insulin glargine plus placebo. BYETTA is not indicated for the management of obesity and weight loss was a secondary endpoint in the trial. Change in fasting glucose and hypoglycemia incidence were similar between treatment groups.

Thirteen BYETTA recipients and one placebo recipient (9 percent vs. 1 percent) discontinued the study because of adverse events (p less than 0.010); rates of nausea (41 percent vs. 8 percent), diarrhea (18 percent vs. 8 percent), vomiting (18 percent vs. 4 percent), headache (14 percent vs. 4 percent) and constipation (10 percent vs. 2 percent) were higher with BYETTA than with placebo. Major hypoglycemia occurred twice in one patient receiving insulin glargine without BYETTA.

In November 2011, Lilly and Amylin announced that they amicably terminated their decade-long collaboration. As part of the transition plan outside the U.S., Amylin will assume responsibility for exenatide product commercialization efforts on a market-by-market basis by the end of 2013. Amylin will work with Lilly on plans for markets outside the U.S. during the transition period. Amylin intends to provide uninterrupted patient supply in all markets where exenatide products are launched, as well as additional markets in the future. Both companies are committed to ensuring a seamless transition of global product responsibility to Amylin while maintaining continuity of patient care. Amylin anticipates working with one or more partners outside the U.S. in order to maximize the global potential of this innovative molecule and achieve greater operational flexibility and efficiency.

About Diabetes

Diabetes affects an estimated 347 million adults worldwide and nearly 26 million people in the U.S.^{(2),(3)} Approximately 90-95 percent of those affected have type 2 diabetes. In the U.S., diabetes costs more than \$174 billion per year in direct and indirect medical expenses.⁽⁴⁾

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.⁽⁵⁾ In addition, 85 percent of type 2 diabetes patients are overweight and 55 percent are considered obese.⁽⁶⁾ Data indicate that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.^{(7),(8)}

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. It can also be used with metformin, a sulfonylurea, a thiazolidinedione or Lantus® (insulin glargine), which is a long-acting insulin.

BYETTA is not insulin and should not be taken instead of insulin. BYETTA should not be taken with short- and/or rapid-acting insulin. BYETTA is not for people with type 1 diabetes or people with diabetic ketoacidosis. BYETTA has not been studied in patients with a history of pancreatitis. Other antidiabetic therapies should be considered for these patients.

BYETTA provides sustained A1C control 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 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. Patients should be observed for signs and symptoms of pancreatitis after initiation or dose escalation of BYETTA.

The risk of getting low blood sugar is higher if BYETTA is taken with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. The dose of sulfonylurea or insulin may need to be lowered while BYETTA is used. BYETTA should not be used in people who have severe kidney problems and may cause or worsen problems with kidney function, including kidney failure. 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. 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, feeling jittery, dizziness, headache, acid stomach, constipation and weakness. 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 Pharmaceuticals

Amylin Pharmaceuticals is a biopharmaceutical company dedicated to improving lives of patients through the discovery, development and commercialization of innovative medicines. Amylin is committed to delivering novel therapies that transform the way diabetes and related metabolic disorders are treated. Amylin is headquartered in San Diego and has a commercial manufacturing facility in Ohio. More information about Amylin Pharmaceuticals is available at www.amylin.com.

About Lilly

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.

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 the revenues generated from BYETTA may be affected by competition; unexpected new data; safety and technical issues; clinical trials not confirming previous results or not being predictive of real-world use; pre-clinical trials not predicting future results; label expansion requests not being submitted in a timely manner or receiving regulatory approval; approved label expansions not producing the results we expect, 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 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.

P-LLY

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