



## **Type 2 Diabetes Patients With Long-Standing Disease Achieved Glycemic Control When BYETTA(R) Was Added to Lantus(R)**

### **Study Presented at ADA 2010**

ORLANDO, Fla., June 26, 2010 /PRNewswire via COMTEX News Network/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) and Eli Lilly and Company (NYSE: LLY) today announced results from the first double-blind, placebo-controlled clinical study to evaluate BYETTA(R) (exenatide) injection added to Lantus(R) (insulin glargine), which showed patients with type 2 diabetes achieved glucose targets without weight gain or increasing their risk of hypoglycemia. These findings were presented at the 70th Annual Scientific Sessions of the American Diabetes Association (ADA) in Orlando, Fla.

In the study, 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 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. Weight decreased in patients adding BYETTA by 4 pounds, compared with an increase of 2 pounds in patients treated with insulin alone. Fasting plasma glucose and hypoglycemia were similar between treatment groups.

"Even in this population of patients who were poorly controlled on insulin therapy, the addition of BYETTA to optimized basal insulin therapy provided exactly what we hoped for - improved control of blood sugar throughout the day, weight loss and no increased risk of hypoglycemia as compared to optimized basal insulin treatment alone," said John Buse, M.D., Ph.D., Professor of Medicine, Director of the Diabetes Care Center, and Chief of the Division of Endocrinology at the University of North Carolina School of Medicine in Chapel Hill. "This study showed BYETTA may provide a complementary addition to basal insulin for these hard-to-treat type 2 diabetes patients."

Results from this study will form the basis for a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA). The filing is planned for the end of 2010.

### **Study Design and Findings**

The double-blind, placebo-controlled study enrolled 261 patients (mean age: 59 years old; weight: 208 pounds; A1C: 8.4 percent; diabetes duration: 12 years; insulin dose 48 units) who were randomized to BYETTA 10 micrograms (n=137) or placebo (n=122). Groups were generally comparable at baseline. Insulin dose was decreased by 20 percent if a patient's A1C was  $\leq$  8 percent or maintained if a patient's A1C was  $>$  8 percent for five weeks, then titrated to achieve a target fasting glucose of  $<$  100 mg/dL. Primary endpoint was change in A1C, a measure of average blood sugar over three months. Continuous glucose monitoring (n=23) and 7-point glucose profiles demonstrated significant postprandial effects with BYETTA compared with insulin alone. Insulin dose increased more in the placebo group ( $20 \pm 2$  units) than in the BYETTA group ( $13 \pm 2$  units) to achieve the fasting glucose target.

### **Safety Profile**

Nausea was the most common 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.

### **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 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 indicate that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.(vi,vii)

## About BYETTA(R) (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 available at [www.BYETTA.com](http://www.BYETTA.com).

## Important Safety Information for BYETTA(R) (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](http://www.byetta.com/pi)) and Medication Guide ([www.byetta.com/mg](http://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(R) (pramlintide acetate) injection and BYETTA(R) (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, California. Further information on Amylin Pharmaceuticals is available at [www.amylin.com](http://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](http://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, Ind., 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](http://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; the study results mentioned in this press release not being predictive of real-world results; 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 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(R) is a registered trademark of Amylin Pharmaceuticals, Inc. All other marks are the marks of their respective owners.

**P-LLY**

(i) The International Diabetes Federation Diabetes Atlas. Available at: <http://www.diabetesatlas.org/content/some-285-million-people-worldwide-will-live-diabetes-2010>. Accessed June 19, 2010.

(ii) Diabetes Statistics. American Diabetes Association. Available at: <http://www.diabetes.org/diabetes-basics/diabetes-statistics/>. Accessed June 19, 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 June 19, 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.

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(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 and 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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