# BYETTA Approved for Expanded Use as First-Line Treatment for Type 2 Diabetes

## Prescribing Information Also Includes Updated Safety Information

SAN DIEGO and INDIANAPOLIS, Oct 30, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Amylin Pharmaceuticals, Inc., (Nasdaq: AMLN) and Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for BYETTA(R) (exenatide) injection. BYETTA is now approved for use as a stand-alone medication (monotherapy) along with diet and exercise to improve glycemic control in adults with type 2 diabetes. Previously, it was approved for use only in patients who were also taking other common diabetes medications and had not achieved adequate glycemic control.

"The expanded indication gives physicians the option to prescribe BYETTA as a first-line treatment, increasing the number of patients who may benefit from the medication and providing an opportunity to treat patients with BYETTA earlier in the disease," said Orville G. Kolterman, M.D., senior vice president of research and development, Amylin Pharmaceuticals. "Type 2 diabetes is a complex disease, so it is essential that healthcare professionals and their patients have a wide array of treatments that can effectively control blood glucose levels."

The approval of BYETTA as a monotherapy treatment was based on a clinical study of patients with type 2 diabetes who were unable to achieve glycemic control through diet and exercise alone. Study findings showed that patients treated with 5 mcg or 10 mcg of BYETTA as monotherapy reduced their A1C, a measure of average blood sugar over three months, by 0.7 percentage points and 0.9 percentage points, respectively, and lost 6.0 pounds and 6.4 pounds, respectively. Results of this study were published in *Clinical Therapeutics* in August 2008.(i)

Among treatment-emergent adverse events, nausea was reported with the greatest incidence (5 mcg, 3 percent; 10 mcg, 13 percent). Hypoglycemia was reported in 5 percent of patients taking 5 mcg and 4 percent of patients taking 10 mcg, with no severe hypoglycemic events.

In addition to the monotherapy indication, the FDA approved changes to the BYETTA Prescribing Information to incorporate updated safety information, including pancreatitis-related language added to the Warnings and Precautions section. This update addresses the alert issued by the FDA in August 2008. The new label also expands upon existing language regarding use of BYETTA in patients with renal impairment. In addition, the label has been amended to match the format the FDA currently uses for Prescribing Information. This label update is being communicated to physicians via a "Dear Healthcare Professional" letter, which will be available at *www.BYETTA.com*.

"Patient safety is our foremost concern at Amylin and Lilly, and the BYETTA Prescribing Information represents an important way to communicate the information that healthcare professionals and patients need in order to use the medication safely and effectively," Kolterman continued. "Thus, the updated label offers the most current information about the benefit-risk profile of BYETTA as a foundational therapeutic choice for people with type 2 diabetes."

BYETTA has been used by more than one million patients since market introduction in 2005. It has a proven history with more than 10 million prescriptions written and 6.5 years of clinical experience.

*About Diabetes*

Diabetes affects more than 24 million people in the United States and an estimated 246 million adults worldwide.(ii,iii) Approximately 90-95 percent of those affected have type 2 diabetes. Diabetes is the fifth leading cause of death by disease in the United States and costs approximately $174 billion per year in direct and indirect medical expenses.(iv)

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.(v)( )In addition, 85 percent of type 2 diabetes patients are overweight and 55 percent are considered obese.(vi) Data indicate that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.(vii,viii)

*About BYETTA*(R) *(exenatide) injection*

BYETTA is the first and only 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. For full prescribing information, visit *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 Prescribing Information and Medication Guide, visit www.BYETTA.com.*

*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*.

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, 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*.

*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; 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. 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.*

P-LLY

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(iii) "All About Diabetes." American Diabetes Association. Available at: *http://www.diabetes.org/about-diabetes.jsp*. Accessed Oct. 2, 2009.

(iv) "Direct and Indirect Costs of Diabetes in the United States." American Diabetes Association. Available at: *http://www.diabetes.org/diabetes-statistics/cost-of-diabetes-in-us.jsp*. Accessed Oct. 2, 2009.

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(vi) 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.

(vii) Nutrition Recommendations and Interventions for Diabetes: a position statement of the American Diabetes Association. *Diabetes Care*. 2007;30 Suppl 1:S48-65.

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SOURCE Amylin Pharmaceuticals, Inc.

http://www.amylin.com