Amylin Pharmaceuticals and Eli Lilly and Company Statement on FDA's BYETTA(R) (Exenatide) Injection Update

SAN DIEGO and INDIANAPOLIS, Nov 02, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Amylin Pharmaceuticals, Inc., (Nasdaq: AMLN) and Eli Lilly and Company (NYSE: LLY) today issued the following statement in response to the U.S. Food and Drug Administration (FDA) update on BYETTA(R) (exenatide) injection.

"The FDA update issued today aligns with the BYETTA label approved last week. The current label reflects our understanding of post-marketing reports of renal events and provides physicians with updated guidance about appropriate use in patients with renal conditions. There is no evidence from preclinical and clinical studies that BYETTA has any direct toxic effect on the kidney," said Orville G. Kolterman, M.D., senior vice president of research and development, Amylin Pharmaceuticals. "Post-marketing reports of serious changes in renal function have been rare and usually complicated by other factors that could have contributed to the kidney problems. It is also important to note that diabetes is the leading cause of kidney failure. Information about use of BYETTA in patients with impaired renal function was included in the initial product label in 2005 and was updated in 2007. We remain committed to working closely with the FDA to ensure that physicians and patients are provided with accurate information about any potential risks associated with the use of our products."

On October 30, the FDA approved an expanded indication for BYETTA as a stand-alone medication (monotherapy) along with diet and exercise to improve glycemic control in adults with type 2 diabetes. In addition to the monotherapy indication, the FDA approved changes to the BYETTA Prescribing Information to incorporate updated safety information. The new label expands upon existing language regarding use of BYETTA in patients with renal impairment, which Amylin and Lilly updated in September 2007 to include additional language regarding renal adverse events. It specifies that BYETTA should not be used in patients with severe renal impairment or end-stage renal disease and should be used with caution in patients with renal transplantation. It also specifies that because BYETTA may induce nausea and vomiting with transient hypovolemia (low blood volume), treatment may worsen renal function. This update was communicated to physicians via a "Dear Healthcare Professional" letter, which is available at *www.BYETTA.com*.

BYETTA has extensive post-marketing experience and a well-documented safety profile. 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.(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 United States 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 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.

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(i) The International Diabetes Federation Diabetes Atlas. Available at: http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A. Accessed Oct. 2, 2009.

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

(iii) "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.

(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.

SOURCE Amylin Pharmaceuticals, Inc.

http://www.amylin.com