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FDA Approves BYETTA(R) (exenatide) Injection for Expanded Combination Use

Millions of People Using Thiazolidinediones Now Have New Treatment Option to Manage Type 2 Diabetes

SAN DIEGO and INDIANAPOLIS, Dec 22, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) and Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) has approved BYETTA(R) (exenatide) injection as an add-on therapy to improve blood sugar control in people with type 2 diabetes who have not achieved adequate control on a thiazolidinedione (TZD). Healthcare professionals will be educated on this additional use for BYETTA in the coming weeks.

In a clinical trial designed to evaluate BYETTA for use in combination with a TZD, 62 percent of patients who added BYETTA to their existing medicines achieved an A1C (a measure of blood glucose levels over time) of 7 percent or less, compared to 16 percent of the patients on placebo. People taking BYETTA also lost an average of 3.3 pounds over 16 weeks, compared to an average weight reduction of 0.4 pounds in the other group. The most common adverse event associated with BYETTA was nausea (40 percent)(1)(2).

"Due to the progressive nature of type 2 diabetes, previous approaches to management frequently failed to achieve target levels of A1C, or resulted in subsequent failure over one to three years," said Dr. Robert Ratner, Vice President for Scientific Affairs at the MedStar Research Institute in Washington, DC. "The combination of exenatide with metformin, sulfonylureas, or TZDs not only expands our options to achieve optimal glycemic control, but does so with accompanying weight loss."

BYETTA improves blood sugar control by lowering both post-meal and fasting (early morning) glucose levels resulting in better long-term control as measured by A1C. BYETTA controls blood sugar through several physiologic actions, including the stimulation of insulin secretion only when blood sugar is high. BYETTA restores the first-phase insulin response (an activity of the cells in the pancreas that is lost in patients who have type 2 diabetes), decreases glucose output from the liver, regulates gastric emptying, and decreases food intake. The majority of patients in long-term BYETTA clinical studies also experienced weight loss.

"Almost half a million people with type 2 diabetes have used BYETTA to help reduce their blood sugar," said Ginger L. Graham, Chief Executive Officer, Amylin Pharmaceuticals. "Now, even more people -- those who use another common category of oral medicines, TZDs -- have a new treatment option and have the opportunity to benefit from the unique clinical benefits of BYETTA."

"There are two core defects to type 2 diabetes, beta cell failure and insulin resistance," said Vince Mihalik, Global Brand Development Leader for Diabetes and Endocrine, Lilly. "The ability of BYETTA to improve beta cell responsiveness and lower weight complements the TZD effect on insulin resistance very nicely."

About BYETTA

BYETTA is the first in a new class of drugs for the treatment of type 2 diabetes called incretin mimetics. 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 intestine, liver, pancreas and brain(3). BYETTA is approved by the FDA for use by people with type 2 diabetes who are unsuccessful at controlling their blood sugar levels despite using the commonly prescribed oral medications metformin, a sulfonylurea, or a thiazolidinedione. For full prescribing information, visit www.BYETTA.com.

About Diabetes

Diabetes affects more than 20 million in the United States and an estimated 194 million adults worldwide(4)(5). Approximately 90-95 percent of those affected have type 2 diabetes. People who have type 2 diabetes either do not produce enough insulin and/or the cells in the body do not respond normally to insulin. Diabetes is the fifth leading cause of death by disease in the United States and costs approximately $132 billion per year in direct and indirect medical expenses(6). Type 2 diabetes usually occurs in adults over the age of 40, but is increasingly common in younger people.

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 target A1C levels (the target is less than 7.0%, according to American Diabetes Association guidelines) with their current treatment regimen(7).

Important Safety Information for BYETTA(R) (exenatide) injection

BYETTA improves blood sugar control in patients with type 2 diabetes who are taking metformin, a sulfonylurea, a thiazolidinedione, a combination of metformin and a sulfonylurea, or a combination of metformin and a thiazolidinedione, but have not achieved adequate glycemic control. BYETTA is not a substitute for insulin in patients whose diabetes requires insulin treatment. BYETTA is not recommended for use in patients with problems digesting food or those who have severe disease of the stomach or kidney. Before using BYETTA, patients should tell their healthcare provider if they are pregnant, plan to become pregnant, or are breastfeeding. BYETTA has not been studied in children.

Sulfonylureas, commonly used products among patients with type 2 diabetes, can cause hypoglycemia (low blood sugar). Therefore, when BYETTA is used with a medicine that contains a sulfonylurea, there is an increased risk of this possible side effect. To reduce this possibility, the dose of sulfonylurea medicine may need to be reduced while using BYETTA. Other common side effects with BYETTA include nausea, vomiting, diarrhea, dizziness, headache, feeling jittery, and acid stomach. Nausea is most common when first starting BYETTA, but decreases over time in most patients. BYETTA may reduce appetite, the amount of food eaten, and body weight, however no changes in dose are needed for these side effects. These are not all the side effects with BYETTA. A healthcare provider should be consulted about any side effect that is bothersome or does not go away.

For complete safety profile and other important prescribing considerations, visit www.BYETTA.com.

About Amylin and Lilly

Amylin Pharmaceuticals is a biopharmaceutical company committed to improving lives 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, obesity and cardiovascular disease. Amylin is located in San Diego, California with over 1,500 employees nationwide. Further information on Amylin Pharmaceuticals is available at www.amylin.com.

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 health care 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 first-in-class and best-in-class 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 additional indications for BYETTA may not be received and/or that BYETTA may be affected by unexpected new data or technical issues. The potential for BYETTA may also be affected by competition, government and commercial reimbursement and pricing decisions, the pace of market acceptance and any issues related to manufacturing and supply. These and additional risks and uncertainties are described more fully in Amylin's and Lilly's most recently filed SEC documents such as their Quarterly Reports on Form 10-Q. Amylin and Lilly undertake no duty to update these forward-looking statements.

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