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# BYETTA(R) (exenatide) Approved for Treatment of Type 2 Diabetes by European Commission

## - Exenatide is the first in a new class of medicines known as incretin mimetics -

INDIANAPOLIS, and SAN DIEGO, Nov 21, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) and Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) today announced that the European Commission has granted marketing authorization for BYETTA(R) (exenatide) for the treatment of type 2 diabetes. The approval decision follows a positive opinion adopted September 21, 2006, by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency. Lilly and Amylin anticipate launching exenatide in Europe in 2007.

Exenatide is now approved in the European Union as adjunctive therapy to improve blood sugar control in patients with type 2 diabetes who have not achieved adequate glycaemic control on maximally tolerated doses of metformin and/or a sulfonylurea, two common oral diabetes medications. Exenatide is the first in a new class of antidiabetic medicines known as incretin mimetics.

The European Commission based its decision on the review and evaluation of a comprehensive data package for exenatide that comprised results of 35 studies and included nearly 4,000 patients with type 2 diabetes across more than 20 countries. In the clinical trials, exenatide was shown to help patients improve long-term blood sugar control by lowering both fasting and postprandial glucose levels (peak levels after meals). Long-term blood sugar control was measured by haemoglobin A1c, which measures a person's average glucose level over a three-month period and is often used by health care providers to assess blood glucose management. In addition, most patients experienced progressive reductions in weight, a secondary endpoint of the studies.

Studies that compared exenatide to insulin showed that exenatide can control blood sugar as effectively as several kinds of insulin often used in patients failing to respond to oral agents.(1,2,3) On average, patients treated with exenatide lost weight, whereas treatment with insulin was associated with weight gain.

Exenatide has been shown to work through several actions, including the stimulation of insulin secretion only when blood sugar is above normal and by restoring the first-phase insulin response. First-phase insulin response is a normal process of insulin-producing cells in the pancreas that is lost in patients who develop type 2 diabetes.

"The availability of a treatment that lowers blood sugar to a healthy range, lowers weight, and has the potential to help restore the response of the body's insulin-producing cells is an exciting advance for patients with type 2 diabetes," said Professor Anthony Barnett of the University of Birmingham and Birmingham Heartlands Hospital in the United Kingdom and an investigator for the exenatide clinical studies. "Exenatide is an appropriate option to consider when patients cannot control their blood sugar using one or more oral medications."

"More than 48 million people in Europe are estimated to have diabetes," said Abbas Hussain, president of European operations for Lilly. "The rapid increase in the prevalence of diabetes and the need for innovative new treatments has never been more critical than it is today. This approval of exenatide is a major step forward in giving health care professionals and patients in all European countries a new treatment option for the management of type 2 diabetes. Diabetes is an area of tremendous unmet medical need, and we are committed to being a leader in developing new therapies for patients."

Exenatide is formulated for self-administration as a fixed dose, subcutaneous injection given prior to the morning and evening meals, or the two main meals of the day. Exenatide does not require dose adjustment due to the effects of exercise, food intake, or blood glucose monitoring results. Exenatide is available in both a 5-microgram per dose and 10-microgram per dose pre-filled pen-delivery system. Patients will begin on the 5-microgram dose for one month and then can move to the 10-microgram dose to further improve their glycaemic control.

Exenatide has been shown to be effective in clinical trials. Exenatide was generally well tolerated across the trials. The most common adverse event reported was mild to moderate nausea that was dose dependent. With continued therapy, the frequency and severity of nausea decreased over time in most patients. Consistent with exenatide's self-regulating action, exenatide stimulates the release of insulin only when needed, thereby reducing the potential for hypoglycaemia (low blood sugar).

About BYETTA

Exenatide is the first in a new class of medicines known as incretin mimetics and was approved for use in the United States by the U.S. Food and Drug Administration in April 2005 as an adjunctive therapy to improve blood sugar control in patients with type 2 diabetes who have not achieved adequate glycaemic control on metformin and/or a sulfonylurea, two common oral diabetes medications. Exenatide exhibits many of the same effects as the human incretin hormone glucagon-like peptide-1 (GLP-1). GLP-1, secreted in response to food intake, has multiple effects on the intestine, liver, pancreas and brain that work in concert to regulate blood sugar.(4)

About Incretin Mimetics

Incretin mimetics are a new class of treatment in the fight against diabetes. An incretin mimetic works to mimic the antidiabetic or glucose- lowering actions of naturally occurring human hormones called incretins. These actions include stimulating the body's ability to produce insulin in response to elevated levels of blood sugar, inhibiting the release of a hormone called glucagon following meals, slowing the rate at which nutrients are absorbed into the bloodstream and reducing food intake. Exenatide is the first FDA-approved incretin mimetic.

About Diabetes

Diabetes affects an estimated 194 million adults worldwide(5) and around 48.4 million in Europe.(6) Approximately 90 to 95 percent of those are affected by type 2 diabetes, a condition characterized by failure of the pancreatic beta cells to adequately respond to the increased demands for insulin that occur as a result of obesity-related insulin resistance.(7) Type 2 diabetes usually occurs in adults over the age of 40, but is increasingly common in younger people.(6) In virtually every developed society, diabetes is ranked among the leading causes of blindness, renal failure and lower limb amputation, as well as death through its effects on cardiovascular disease (70-80 percent of people with diabetes die of cardiovascular disease)(8). The calculated estimates of the costs of diabetes care in Europe amount to 42.8 million International Dollars per year.(9)

About Lilly and Amylin

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.

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, IN, Lilly provides answers -- through medicines and information -- for some of the world's most urgent medical needs.

Amylin Pharmaceuticals is a biopharmaceutical company committed to improving lives through the discovery, development and commercialization of innovative medicines. 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 1400 employees.

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 exenatide may not prove to be an important new therapeutic option, or exenatide may be affected by unexpected new data or technical issues. The potential for exenatide may also be affected by 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 and Lilly's most recently filed SEC documents such as their Quarterly Reports on Form 10-Q. Amylin and Lilly disclaim any obligation to update these forward-looking statements.

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SOURCE Eli Lilly and Company; Amylin Pharmaceuticals, Inc.

Derin Denham of Eli Lilly and Company, +1-317-277-6749, mobile: +1-317-370-1435; or
Alice Bahner of Amylin Pharmaceuticals, Inc., +1-858-642-7272, mobile:
+1-858-232-9072

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