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Exenatide Receives Positive Opinion From the European Committee for Medicinal Products for Human Use for the Treatment of Type 2 Diabetes

- The first medicine in a new class of treatments known as incretin mimetics -

INDIANAPOLIS and SAN DIEGO, Sept 21, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) and Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Evaluation Agency (EMA) has issued a positive opinion recommending approval of exenatide for the treatment of type 2 diabetes. If approved, this new medicine for type 2 diabetes is planned to be marketed throughout the European Union under the proposed brand name BYETTA(R). Marketing authorization by the European Commission is expected later this year.

Amylin and Lilly are seeking approval of exenatide as an adjunctive therapy to improve blood sugar control in patients with type 2 diabetes who have not achieved adequate control on metformin and/or sulfonylurea, two common oral diabetes medications.

"Exenatide is an exciting treatment option for patients with type 2 diabetes who cannot control their blood sugar level effectively using the common oral medications metformin and/or sulfonylurea," said Lorenzo Tallarigo, M.D., president international operations at Lilly. "It also marks an important milestone for Amylin and Lilly in the fight against the worldwide diabetes epidemic."

"We are extremely pleased by the CHMP's recommendation for approval of exenatide in Europe. This positive opinion validates the benefit to risk profile seen in clinical trials for this new class of antidiabetic agents," said James Malone, M.D., global medical director at Lilly. "Exenatide is another example of our commitment to provide innovative treatments for patients with diabetes."

The submission package to support the safety and efficacy profile of BYETTA consisted of data collected from 35 studies and included nearly 4,000 patients with type 2 diabetes treated with exenatide across more than 20 countries. Three of the studies compared exenatide to insulin and showed that exenatide can control blood sugar as effectively as insulin.(1, 2, 3) Most patients in the exenatide clinical studies also experienced significant reductions in weight.

About exenatide

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 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 anti-diabetic 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 1250 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, European approval for exenatide may not be received 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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