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Long-Term Data on Exenatide Show Sustained Improvements in Glucose Control and Progressive Weight Reduction in People With Type 2 Diabetes

-- Improvements in cardiovascular risk factors were also observed --

ATHENS, Greece, Sept. 12 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Amylin Pharmaceuticals, Inc., (Nasdaq: AMLN) today presented results from a study indicating that the investigational compound exenatide showed sustained improvements in blood sugar control and progressive weight reduction through two years of therapy for people with type 2 diabetes failing to achieve acceptable blood sugar control on metformin and/or a sulfonylurea, two commonly-used oral diabetes medications.

Additional data were presented showing improvements in markers associated with cardiovascular risk factors, including lipids and blood pressure through a year-and-a-half of treatment. The findings were presented at the 41st annual meeting of the European Association for the Study of Diabetes in Athens, Greece.

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 on 28 April 2005 for the treatment of type 2 diabetes. The U.S. is the first country in the world that has received regulatory approval for exenatide.

"Findings from these long-term data demonstrate that exenatide may have unique benefits for patients with type 2 diabetes who had previously struggled to manage the disease effectively," said Prof. Francesco Giorgino, M.D., Chief, Division of Endocrinology and Metabolic Diseases, University Hospital, and Professor of Endocrinology and Metabolism, University of Bari, Italy, who presented the data in a press briefing at EASD. "The benefits associated with weight reduction are particularly significant given that many therapies for type 2 diabetes cause weight gain."

Key Findings

Nearly 90 percent of patients completing 30 weeks of therapy in the exenatide pivotal studies elected to continue in an open-label extension where all patients received 10 micrograms of exenatide twice a day. Data collected over two years among 195 patients demonstrated that long-term administration of exenatide in combination with metformin, a sulfonylurea or both, results in sustained reductions in blood sugar and progressive reductions in weight.

Patients in the study (who received 10 micrograms of exenatide twice daily) demonstrated an average reduction from baseline of 1.1 percent in A1C levels, a measure reflecting a person's average blood sugar over a three-month period. The average starting A1C for these patients was 8.2 percent. These same patients also demonstrated reductions in body weight, with an average weight reduction of 5.5 kilograms (11.4 pounds).

In addition to improvements in glucose control and weight, administration of exenatide for 82 weeks resulted in clinically meaningful improvements in cardiovascular risk factors in a group of 265 patients. These included clinically positive changes associated with HDL cholesterol, triglycerides, and blood pressure.

In general, improvements in cardiovascular risk factors appeared greatest in patients who experienced the greatest weight reduction. Side effects, which were predominantly gastrointestinal in nature, were consistent with those observed in patients during the placebo-controlled trials. No new safety signals were observed.

About exenatide

Exenatide is the first in a new class of drugs for the treatment of type 2 diabetes called incretin mimetics and 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 stomach, liver, pancreas and brain that work in concert to regulate blood sugar.⁽¹⁾ Exenatide was approved by the U.S. FDA for use by people in the United States with type 2 diabetes who are unsuccessful at controlling their blood sugar levels despite using the commonly prescribed oral medications metformin, a sulfonylurea or both. The U.S. is the first country in the world that has received regulatory approval for exenatide. It is not approved for use in Europe. Lilly anticipates submissions for regulatory review in other countries in the near future.

About Incretin Mimetics

Incretin mimetics is a new class of therapeutics for use in the fight against type 2 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 U.S. FDA-approved agent of this new class of medications.

About Diabetes

Diabetes affects an estimated 194 million adults worldwide⁽²⁾ and around 48.4 million in Europe.⁽²⁾ Of those affected approximately 85 to 95 percent have type 2 diabetes, a condition where the body does not produce enough insulin and/or the cells in the body do not respond normally to insulin.⁽³⁾ Type 2 diabetes usually occurs in adults over the age of 40, but is increasingly common in younger people.⁽³⁾ 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)⁽⁴⁾. The calculated estimates of the costs of diabetes care in Europe amount to 42.8 million International Dollars per year.⁽⁵⁾

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

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

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 future clinical trials may not replicate previous trial results; risks that exenatide may not prove to be an important new therapeutic option, additional indications 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 Annual Reports on Form 10-K. Amylin and Lilly undertake no duty to update these forward-looking statements.

REFERENCES

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SOURCE Eli Lilly and Company; Amylin Pharmaceuticals, Inc.