



April 29, 2005

## **Amylin and Lilly Announce FDA Approval of BYETTA(TM) (Exenatide) Injection**

Apr 29, 2005 /PRNewswire via COMTEX/ --

--A New First-in-Class Treatment for Patients with Type 2 Diabetes--

SAN DIEGO, Calif. and INDIANAPOLIS, Ind., April 29 /PRNewswire-FirstCall/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), and Eli Lilly and Company (NYSE: LLY) announce that the U.S. Food and Drug Administration (FDA) has approved BYETTA (TM) (exenatide) injection as 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. BYETTA (pronounced bye-A-tuh), the trade name for exenatide, is the first in a new class of medicines known as incretin mimetics. BYETTA will be available to pharmacies by June 1, 2005.

BYETTA improves blood sugar control by lowering both postmeal and fasting glucose levels leading to better long-term control as measured by hemoglobin A1C. BYETTA does this through several actions, including the stimulation of insulin secretion only when blood sugar is high and by restoring the first-phase insulin response, an activity of the insulin-producing cells in the pancreas that is lost in patients who have type 2 diabetes. Most patients in the long-term BYETTA clinical studies also experienced reductions in weight.

"The availability of a treatment that lowers blood sugar 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 Dr. David Kendall, Medical Director at International Diabetes Center in Minneapolis, Minnesota, and an investigator for the BYETTA clinical studies. "BYETTA is a truly unique tool for the management of type 2 diabetes and is an appropriate option to consider when patients cannot control their blood sugar using one or more oral medications."

"Successfully managing diabetes is a daily struggle for millions of Americans," said Ginger L. Graham, President and Chief Executive Officer, Amylin Pharmaceuticals, Inc. "Often, current treatments do not provide adequate blood sugar control leaving patients and caregivers frustrated. BYETTA, a first-in-class medicine, is a new therapy for those who are not able to effectively control their blood sugar with their current oral medications."

"BYETTA offers an exciting new option for people with type 2 diabetes and marks an important milestone for Amylin and Lilly's successful collaboration," said Sidney Taurel, Chairman and Chief Executive Officer, Eli Lilly and Company. "With BYETTA's demonstrated effects on blood sugar and its safety profile, physicians and patients now have a new approach to fight the growing diabetes epidemic."

In addition to approving BYETTA for use as an adjunct to existing oral medicines, the FDA also stated that BYETTA is approvable as a stand-alone therapy (monotherapy) for patients with type 2 diabetes. Any additional data submitted to support a monotherapy indication is expected to receive a six-month review.

BYETTA is formulated for self-administration as a fixed dose, subcutaneous injection given prior to the morning and evening meals. BYETTA will be made available in both a 5-microgram per dose and a 10-microgram per dose prefilled pen-injector device.

### **Safety and Tolerability Information**

In the three 30-week controlled trials, adverse events associated with BYETTA were generally mild to moderate in intensity. The most frequently reported adverse event was mild-to-moderate, dose-dependent nausea. With continued therapy in most patients who initially experienced nausea, the frequency and severity decreased over time.

Patients receiving BYETTA in combination with a sulfonylurea have an increased risk of hypoglycemia; to reduce this risk, reduction in the dose of the sulfonylurea should be considered. In the 30-week controlled clinical trials, hypoglycemia appeared to be dependent on the doses of both BYETTA and a sulfonylurea. Most episodes of hypoglycemia were mild to moderate in intensity and all were resolved with oral administration of carbohydrate. No increased risk of hypoglycemia was observed in the 30-week controlled studies with BYETTA when used in combination with metformin compared to placebo.

Patients should also be advised that treatment with BYETTA may result in a reduction in appetite, food intake, and/or body weight and that there is no need to modify the dosing regimen due to such effects.

BYETTA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, nor is BYETTA a substitute for insulin in insulin-requiring patients. Use of BYETTA is not recommended in patients with end-stage renal disease or severe renal impairment, or in patients with severe gastrointestinal disease. BYETTA should be used with caution in patients receiving oral medications that require rapid gastrointestinal absorption.

For full Prescribing Information, visit [www.BYETTA.com](http://www.BYETTA.com) .

#### About BYETTA

BYETTA 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) BYETTA was 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 both. For full Prescribing Information, visit [www.BYETTA.com](http://www.BYETTA.com) .

#### 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. BYETTA is the first FDA-approved agent of this new class of medications.

#### About Diabetes

Diabetes affects an estimated 194 million adults worldwide(2) and more than 18 million in the United States.(3) Approximately 90 to 95 percent of those affected 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) Diabetes is the fifth leading cause of death by disease in the United States(4) and costs approximately \$132 billion per year in direct and indirect medical expenses. Type 2 diabetes usually occurs in adults over the age of 40, but is increasingly common in younger people.(3)

According to the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60 percent of diabetes patients do not achieve target hemoglobin A1C levels (less than 7 percent according to American Diabetes Association guidelines(5)) with their current treatment regimen.(6)

#### Amylin to Webcast Investor Conference Call

Amylin Pharmaceuticals will webcast a conference call to discuss the BYETTA approval and commercialization plans on Friday, April 29, 2005 at 12:00 p.m. ET (9:00 a.m. PT). Ginger L. Graham, President and Chief Executive Officer of Amylin Pharmaceuticals, will lead the call.

The call will be webcast live through Amylin's corporate website, and a recording will be made available following the close of the call. To access the webcast, please log on to [www.amylin.com](http://www.amylin.com) approximately fifteen minutes prior to the call to register, download and install any necessary audio software. A recording will be available by phone for 24 hours beginning approximately one hour after the close of the call and can be accessed at 888-286-8010 (domestic) or 617-801-6888 (international), conference ID number 65243380.

#### About Amylin and Lilly

Amylin Pharmaceuticals is a biopharmaceutical company committed to improving lives through the discovery, development and commercialization of innovative medicines. Further information on Amylin Pharmaceuticals, its marketed products, and its pipeline in metabolism is available at [www.amylin.com](http://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](http://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](http://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 may not prove to be an important new therapeutic option, additional indications for BYETTA may not be received, BYETTA may not be commercially available when planned and/or may be affected by unexpected new data or technical issues. The potential for BYETTA 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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