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## **Newly Approved First-in-Class Treatment for Type 2 Diabetes Is Now Available**

### **-- Amylin and Lilly Launch BYETTA(TM) (exenatide) injection for type 2 diabetes patients unable to control disease with common oral therapies --**

SAN DIEGO, and INDIANAPOLIS, June 9, 2005 /PRNewswire-FirstCall via COMTEX/ -- BYETTA(TM) (exenatide) injection is now available for Americans struggling to control their type 2 diabetes. BYETTA can help diabetes patients manage blood sugar while potentially losing weight. Recently approved by the Food and Drug Administration (FDA), BYETTA is now available in pharmacies across the country.

Developed by Amylin Pharmaceuticals, Inc., (Nasdaq: AMLN) and Eli Lilly and Company (NYSE: LLY), BYETTA (pronounced bye-A-tuh) is available 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. BYETTA is the first in a new class of diabetes treatment called incretin mimetics. By mimicking the mechanisms of a naturally occurring human hormone, BYETTA is a diabetes self regulating drug that stays in the blood system, working actively only when blood sugar levels are too high. In clinical trials, BYETTA was shown to help patients regulate blood sugar levels. Most patients in the long-term BYETTA clinical studies also experienced reductions in weight.

"For a disease where more than two-thirds of the patients aren't achieving their target blood sugar levels, the availability of BYETTA is a remarkable advancement for the diabetes medical community. BYETTA addresses a core defect of type 2 diabetes, where the body fails to respond normally to food intake, causing blood sugar levels to rise and fluctuate in an unhealthy manner," said Dr. Carol Wysham, Clinical Endocrinologist at Rockwood Clinic in Spokane, Washington and Clinical Assistant Professor of Medicine at University of Washington.

Three different studies published since 2002 demonstrate the public health burden of diabetes and the challenge patients face while trying to achieve adequate blood sugar control. These studies, published by the American Association of Clinical Endocrinologists, the Journal of the American Medical Association and the American Diabetes Association (ADA), show that nearly two-thirds of the 13 million Americans diagnosed with and being treated for diabetes are still not achieving target blood glucose levels recommended by ADA. This collective data further substantiates the urgent need for new treatment options.

"With BYETTA I feel in charge, no longer having to revolve everything around when and what I eat. Not only is my blood sugar under control, but BYETTA has helped me lose weight," said David Anderson, a participant in the clinical trials.

Continuing Amylin's success in innovative therapies and Lilly's leadership in diabetes care, BYETTA offers a promising new approach to type 2 diabetes patients who, despite the number of treatment options available, are still unable to adequately manage the disease.

BYETTA is formulated for easy self-administration as a fixed dose injection given before meals in the morning and in the evening, and is available in pharmacies across the country in both a 5 microgram and a 10 microgram pre-filled pen.

#### **Safety and Tolerability**

Adverse events associated with BYETTA are generally mild to moderate in intensity. In clinical trials, the most frequently reported adverse event was mild-to-moderate, dose-dependent nausea. With continued therapy, the frequency and severity of nausea decreased over time in most patients.

Patients receiving BYETTA in combination with a sulfonylurea may be at a higher risk of hypoglycemia, or low blood sugar. To reduce this risk, lowering the sulfonylurea dosage may be considered. When patients begin taking BYETTA, the symptoms, treatment, and conditions that predispose development of hypoglycemia should be explained to them, and the patient's usual instructions for hypoglycemia management should be reviewed and reinforced.

Patients should also be advised that treatment with BYETTA may lead to 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 is not a substitute for insulin in insulin-requiring patients. BYETTA should not be used in patients with type 1 diabetes.

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 complete safety profile and other important prescribing considerations, 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 intestine, liver, pancreas and brain that work in concert to improve blood sugar.<sup>(1)</sup> 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 agents 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. BYETTA is the first FDA-approved agent of this new class of medications.

#### About Diabetes

Diabetes affects an estimated 194 million adults worldwide<sup>(2)</sup> and more than 18 million in the United States.<sup>(3)</sup> Approximately 90-95 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. 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. 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 diabetes patients do not achieve target A1C levels (less than 7.0% according to American Diabetes Association guidelines) with their current treatment regimen.

#### 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 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 and BYETTA 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.

#### P-LLY

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(2) The International Diabetes Federation Diabetes Atlas. Available at: <http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A>. Accessed April 12, 2005.

(3) Center for Disease Control and Prevention (CDC) National Diabetes Fact Sheet 2005. Available at [http://www.cdc.gov/nccdphp/aag/pdf/aag\\_ddt2005.pdf](http://www.cdc.gov/nccdphp/aag/pdf/aag_ddt2005.pdf). Accessed June 6, 2005.

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SOURCE Eli Lilly and Company; Amylin Pharmaceuticals, Inc.

Jamaison Schuler of Eli Lilly and Company, +1-317-655-2111, cell: +1-317-457-2113; o  
Eric Shearin of Amylin Pharmaceuticals, Inc., +1-858-552-2200, ext. 7177, cell:  
+1-858-699-5514

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