



September 1, 2004

Exenatide New Drug Application Accepted for Review by the FDA

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Amylin Pharmaceuticals, Inc., (Nasdaq: AMLN) and Eli Lilly and Company (NYSE: LLY) today announced that the New Drug Application (NDA) for exenatide has been accepted for review by the Food and Drug Administration (FDA). Exenatide is the first potential therapy in a new class of drugs under investigation for the treatment of type 2 diabetes known as incretin mimetics. The NDA for exenatide was submitted to the FDA on June 29, 2004. The Prescription Drug User Fee Act (PDUFA) goal date is April 30, 2005.

"This is an important step in the regulatory process as we work to transition exenatide from an investigational agent to the marketplace, providing an additional therapy to people living with type 2 diabetes," said Ginger Graham, President and CEO of Amylin Pharmaceuticals. The exenatide NDA is made up of three major components; chemistry and manufacturing, preclinical and clinical. The clinical component of the submission is based on 30-week data from three blinded pivotal trials of exenatide involving more than 1,400 patients who were unable to control their blood sugar on common oral therapies including metformin, sulfonylurea or a combination of both. The submission also includes 52-week open-label data from the extensions of these pivotal studies and from an additional open-label study.

About Diabetes

Diabetes affects an estimated 194 million adults worldwide and more than 18 million in the United States. Approximately 90-95 percent of those affected have type 2 diabetes, in which the body does not produce enough insulin and the cells in the body do not respond normally to the insulin. According to the US Center for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60 percent of diabetes patients do not achieve target A1C levels with their current treatment regimen. According to the ADA, patients with A1Cs above target are more likely to develop diabetes-related complications, such as kidney disease, blindness and heart disease.

About Amylin and Lilly

Amylin Pharmaceuticals is committed to improving the lives of people with diabetes and other metabolic diseases through the discovery, development and commercialization of innovative, cost-effective medicines. Further information on Amylin Pharmaceuticals and its pipeline in metabolism is available at 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

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

This press release contains forward-looking statements, which involve risks and uncertainties. Actual results could differ materially from those discussed or implied in this press release, including risks that the FDA may request additional information or data regarding exenatide, risks that exenatide may not receive FDA approval or that such approval may be delayed or limited, or risks that exenatide may not prove to be commercially successful. These and additional risks and uncertainties are described more fully in Lilly and Amylin's most recently filed SEC documents, such as their annual reports on Form 10-K for the fiscal year ended December 31, 2003 under the heading "Risk Factors Related to Our Business", their subsequently filed Quarterly Reports on Form 10-Q, and Amylin's recently filed Form S-3.

1. The International Diabetes Federation Diabetes Atlas. Available at: <http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A>. Accessed August 31, 2004.
2. American Diabetes Association. Available at: <http://www.diabetes.org/about-diabetes.jsp>. Accessed August 31, 2004.
3. Saaddine JB, Engelgau MM, Beckles GL, Gregg EW, Thompson TJ, Narayan KM. A diabetes report card for the United States: Quality of care in the 1990s. *Ann Intern Med.* 2002; 136:565-574.