



Monotherapy BYETTA(R) Showed Significant Improvement in Glucose Control and Weight Loss in Adults with Type 2 Diabetes

- FDA Submission Planned in First Half of 2008 -

SAN DIEGO and INDIANAPOLIS, Dec 06, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) and Eli Lilly and Company (NYSE: LLY) today announced study results from a 24-week study of monotherapy, or stand-alone, BYETTA (exenatide) injection taken twice daily in drug-naïve patients with type 2 diabetes. Study participants taking 5 mcg or 10 mcg of monotherapy BYETTA twice daily showed significant reductions in A1C (a measure of average blood sugar over 3 months) by 0.7 percentage points and 0.9 percentage points, respectively, from an average baseline A1C ranging from 7.8 to 7.9 percent. In addition, approximately 60 percent of study participants on either 5 mcg or 10 mcg of monotherapy BYETTA at the conclusion of the study had an A1C of 7 percent or less, a common target for good glucose control. The companies plan a regulatory submission to the U.S. Food and Drug Administration (FDA) in the first half of 2008.

In this 24-week, randomized, placebo-controlled study, 232 drug-naïve people with type 2 diabetes were treated with monotherapy BYETTA or placebo. More than 85 percent of study participants in the 5 mcg and 10 mcg arms completed the study. Weight loss from baseline was significant and similar to that observed in previous BYETTA studies.

"The American Diabetes Association's (ADA) clinical guidelines for the treatment of patients with type 2 diabetes are to achieve target glucose control, as well as weight loss in overweight or obese patients," said James Malone, M.D., Global Medical Director, Eli Lilly and Company. "These data are robust and are consistent with data from other trials that support the use of BYETTA before starter insulin. If approved for monotherapy, BYETTA may provide an additional treatment option for physicians to consider earlier in the continuum of care."

There was a low incidence of nausea reported in both treatment arms of the study of approximately 3 and 13 percent in the 5 mcg and 10 mcg arms, respectively. There were no instances of severe hypoglycemia in this study. Overall hypoglycemia observed was similar to that seen in studies where BYETTA was used in conjunction with metformin only.

BYETTA -- the first and only FDA-approved incretin mimetic -- was approved in April 2005 and has been used by more than 700,000 patients since its introduction. BYETTA is indicated as an add-on therapy for use twice a day in adults with type 2 diabetes who are unsuccessful at controlling their blood sugar levels using common oral diabetes medications. This study was conducted following receipt of an approvable letter for a monotherapy indication from the FDA in 2005.

Study Design

The 24-week, randomized study included 232 people with type 2 diabetes who were not achieving adequate glucose control using diet and exercise without previous use of antidiabetes agents. Study participants were randomized to receive subcutaneous injections of placebo, 5 mcg exenatide, or 10 mcg exenatide twice daily without taking any oral antidiabetes agents. Patients randomized to 10 mcg exenatide received 5 mcg injections for the first 4 weeks, and increased to 10 mcg injections for the final 20 weeks.

Full study results will be included in future scientific publications.

About BYETTA(R) (exenatide) injection

BYETTA is the first in a class of drugs called incretin mimetics for the treatment of type 2 diabetes. BYETTA exhibits many of the same effects as the human incretin hormone glucagon-like peptide-1 (GLP-1). GLP-1 improves blood sugar after food intake through multiple effects that work in concert on the stomach, liver, pancreas and brain. BYETTA is approved by the FDA for use by people with type 2 diabetes who are unsuccessful at controlling their blood sugar levels. BYETTA is an add-on therapy for people currently using metformin, a sulfonylurea, or a thiazolidinedione. BYETTA provides sustained A1C control, low incidence of hypoglycemia when used with metformin or a thiazolidinedione, and progressive weight loss. For full prescribing information, visit <http://www.BYETTA.com>.

About Diabetes

Diabetes affects more than 21 million in the United States and an estimated 246 million adults worldwide (1,2). Approximately 90-95 percent of those affected have type 2 diabetes. 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 (3).

According to the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60 percent of people with diabetes do not achieve their target blood sugar levels with their current treatment regimen (4).

Important Safety Information for BYETTA

BYETTA improves blood sugar control in adults with type 2 diabetes. It is used with metformin, a sulfonylurea, or a thiazolidinedione. BYETTA is not a substitute for insulin in patients whose diabetes requires insulin treatment. BYETTA is not recommended for use in patients with severe problems digesting food or those who have severe disease of the stomach or kidney.

When BYETTA is used with a medicine that contains a sulfonylurea, low blood sugar (hypoglycemia) is a possible side effect. To reduce this possibility, the dose of sulfonylurea medicine may need to be reduced while using BYETTA. Other common side effects with BYETTA include nausea, vomiting, diarrhea, dizziness, headache, feeling jittery, and acid stomach. Nausea is most common when first starting BYETTA, but decreases over time in most patients.

If patients experience the following severe and persistent symptoms (alone or in combination): abdominal pain, nausea, vomiting, or diarrhea, they should talk to their healthcare provider because these symptoms could be signs of serious medical conditions. BYETTA may reduce appetite, the amount of food eaten, and body weight. No changes in dose are needed for these side effects. These are not all the side effects with BYETTA. A health care provider should be consulted about any side effect that is bothersome or does not go away.

For complete safety profile and other important prescribing considerations, visit <http://www.BYETTA.com>.

About Amylin and Lilly

Amylin Pharmaceuticals is a biopharmaceutical company committed to improving lives through the discovery, development and commercialization of innovative medicines. Amylin has developed and gained approval for two first-in-class medicines for diabetes. Amylin's research and development activities leverage the company's expertise in metabolism to develop potential therapies to treat diabetes and obesity. Amylin is headquartered in San Diego, California with over 1,800 employees nationwide. Further information about Amylin Pharmaceuticals is available at <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 <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, Indiana, Lilly provides answers -- through medicines and information -- for some of the world's most urgent medical needs. Additional information about Lilly is available at <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 and the revenues generated from BYETTA may be affected by competition, unexpected new data, technical issues, clinical trials not confirming previous results, pre-clinical trials not predicting future results, label expansion requests, including the FDA submission referred to in this press release, not being submitted in a timely manner or receiving regulatory approval, or manufacturing and supply issues. The potential for BYETTA may also be affected by government and commercial reimbursement and pricing decisions, the pace of market acceptance, or scientific, regulatory and other issues and risks inherent in the commercialization of pharmaceutical products. 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 undertake no duty to update these forward-looking statements.

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- (1) The International Diabetes Federation Diabetes Atlas. Available at: <http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A>. Accessed November 27, 2007.
- (2) "All About Diabetes." American Diabetes Association. Available at:

<http://www.diabetes.org/about-diabetes.jsp>. Accessed November 27, 2007.

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- (4) Saydah SH, Fradkin J and Cowie CC. "Poor Control of Risk Factors for Vascular Disease Among Adults with Previously Diagnosed Diabetes." JAMA: 291(3), January 21, 2004.

SOURCE Amylin Pharmaceuticals, Inc.; Eli Lilly and Company

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