



Once-Weekly Exenatide Showed Statistical Superiority in Glucose Control Compared to BYETTA in Head-to-Head Study

- Both Groups Experienced Significant Weight Loss - - New Drug Application Filing Planned by the End of the First Half of 2009 -

SAN DIEGO, INDIANAPOLIS, and CAMBRIDGE, Mass., Oct 31, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced positive results from a 30-week comparator study of once-weekly exenatide long-acting release (LAR) injection and BYETTA(R) (exenatide) injection taken twice daily in patients with type 2 diabetes. Once-weekly exenatide, an investigational drug, showed a statistically significant improvement in A1C of approximately 1.9 percentage points from baseline, compared to an improvement of approximately 1.5 percentage points for BYETTA. Approximately three out of four subjects treated with once-weekly exenatide achieved an A1C of 7 percent or less. A1C of less than 7 percent is the target for good glucose control as recommended by the American Diabetes Association.

After 30 weeks of treatment, both once-weekly exenatide and BYETTA treatment resulted in an average weight loss of approximately eight pounds. Nearly 90 percent of subjects in both groups completed the study, which enrolled patients not achieving adequate glucose control with either diet and exercise or with use of oral glucose-lowering agents. The companies anticipate a regulatory submission to the U.S. Food and Drug Administration (FDA) by the end of the first half of 2009.

"Together with our collaboration partners Lilly and Alkermes, we are pleased that use of once-weekly exenatide met the primary endpoint with a greater reduction in A1C than BYETTA and with significant weight loss, both key measures of success in the management of type 2 diabetes," stated Orville G. Kolterman, M.D., Senior Vice President Clinical and Regulatory Affairs, Amylin Pharmaceuticals. "These data confirm the benefits of BYETTA as an important treatment option and suggest that, if approved, once-weekly exenatide has the potential to help patients improve their diabetes management. With these safety and efficacy data in hand, we are working diligently to complete the remaining steps required for our once-weekly exenatide regulatory submission by the end of the first half of 2009, and will make every effort to bring this therapy to patients as quickly as possible."

There was no major or severe hypoglycemia regardless of background therapy. As expected based on prior BYETTA studies, minor hypoglycemia with once-weekly exenatide use was limited to subjects using background sulfonylurea therapy. Once-weekly exenatide was associated with approximately 30 percent less nausea than BYETTA. Approximately one out of five subjects receiving once-weekly exenatide reported treatment-related nausea during the 30-week study. In both groups nausea was predominantly mild and transient. The antibody profile of subjects treated in this study was consistent with the previously reported profiles of BYETTA and once-weekly exenatide.

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 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.

Once-weekly exenatide uses a proprietary technology for long-acting medications developed by Alkermes. The technology encapsulates active medication into polymer-based microspheres that are injected into the body where they degrade slowly, gradually releasing the drug at a carefully controlled rate.

Study Design

The 30-week, open-label, noninferiority study included 295 subjects with type 2 diabetes who were not achieving adequate glucose control using diet and exercise with or without the use of one or more oral antidiabetic agents. Subjects were randomized to receive subcutaneous injections of either once-weekly exenatide 2.0 milligrams or BYETTA taken twice daily as outlined in the approved label. Subjects in both groups who completed the randomized portion of the study continued in the open-ended portion of the study receiving once-weekly exenatide.

Full study results will be included in future scientific publications.

Webcast Investor Conference Call

Amylin Pharmaceuticals will webcast a conference call to discuss these study results today, Wednesday, October 31 at 8:30 a.m. ET (5:30 a.m. PT). Daniel M. Bradbury, 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 approximately fifteen minutes prior to the call to register, download and install any necessary audio software. For those without access to the Internet, the live call may be accessed by phone by calling (866) 356-3095 (domestic) or (617) 597-5391 (international), passcode 19644079. A replay of the call will also 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), passcode 23209035.

About Diabetes

Diabetes affects more than 20 million people in the U.S. 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). Approximately 90 percent of people with diabetes are obese or overweight(4).

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 blood sugar levels with their current treatment regimen(5). Nearly half of newly treated patients with diabetes do not adhere to their treatment regimen(6).

About BYETTA(R) (exenatide) injection

BYETTA is the first in a class of drugs for the treatment of type 2 diabetes called incretin mimetics. 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 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 www.BYETTA.com.

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 www.BYETTA.com.

About Amylin, Lilly, and Alkermes

Amylin, Lilly, and Alkermes are working together to develop exenatide long-acting release injection, a subcutaneous injection of exenatide for the treatment of type 2 diabetes based on Alkermes' proprietary injectable long-acting release technology. Once-weekly exenatide has not been approved by the FDA for marketing in the United States or by regulatory agencies elsewhere in the world.

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, SYMLIN(R) (pramlintide acetate) injection and BYETTA(R) (exenatide) injection. 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 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, 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 www.lilly.com.

Alkermes, Inc. is a biotechnology company that develops innovative medicines designed to yield better therapeutic outcomes and improve the lives of patients with serious disease. Alkermes currently has two commercial products: RISPERDAL(R) CONSTA(R) [(risperidone) long-acting injection], the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, and marketed worldwide by Janssen-Cilag (Janssen, L.P.), a wholly owned division of Johnson & Johnson; and VIVITROL(R) (naltrexone for extended-release injectable suspension) the first and only once-monthly injectable medication approved for the treatment of alcohol dependence and marketed in the U.S. primarily by Cephalon, Inc. Alkermes' pipeline includes extended-release injectable, pulmonary, and oral products for the treatment of prevalent, chronic diseases such as central nervous system disorders, addiction and diabetes. Alkermes' headquarters are in Cambridge, Massachusetts, and it operates research and manufacturing facilities in Massachusetts and Ohio.

This press release contains forward-looking statements, which involve risks and uncertainties within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements are neither promises nor guarantees, and the businesses of Amylin, Lilly and Alkermes are subject to significant risks and uncertainties. There can be no assurance that actual results will not differ materially from the forward-looking statements discussed in this press release. These forward-looking statements include risks and uncertainties, including but not limited to, that current or future clinical trials will confirm previous results; risks and uncertainties that the results from the clinical trial discussed in this press release will generate clinical data that could form the basis of a new drug application (NDA) submission; risks and uncertainties that Amylin will be able to complete manufacturing scale-up and construction and validation of its manufacturing facility on a timely basis, or at all; risks and uncertainties regarding the timing of the NDA filing referred to in this release; risks and uncertainties inherent in the collaboration with and dependence upon Lilly, Amylin and/or Alkermes; risks and uncertainties regarding the drug discovery and development process, including whether once-weekly exenatide will receive regulatory approvals, be commercialized or prove to be commercially successful. These and additional risks and uncertainties are described more fully in Amylin, Lilly and Alkermes' filings with the United States Securities and Exchange Commission. The parties undertake no duty to update forward-looking statements.

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