DURATION-4 Study Results: BYDUREON Efficacy and Tolerability Profile Extended to Monotherapy Treatment

SAN DIEGO, INDIANAPOLIS, and WALTHAM, Mass., June 15, 2010 /PRNewswire via COMTEX News Network/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced results from DURATION-4, the fourth in a series of studies designed to test the superiority of BYDUREON(TM) (exenatide extended-release for injectable suspension), an investigational type 2 diabetes therapy, as compared to other type 2 diabetes medications.

This 26-week clinical study compared BYDUREON monotherapy to Januvia(R) (sitagliptin), Actos(R) (pioglitazone HCI) or metformin, three oral type 2 diabetes medications commonly prescribed early in the treatment of type 2 diabetes. Study participants were not achieving adequate A1C control using diet and exercise, and were not on any diabetes therapy when they entered the study. A1C is a measure of average blood sugar over three months. After 26 weeks of treatment, patients randomized to BYDUREON experienced a reduction in A1C of 1.5 percentage points from baseline, which was significantly greater than the reduction of 1.2 percentage points for Januvia. Patients randomized to metformin experienced a reduction in A1C of 1.5 percentage points, and patients receiving Actos experienced a reduction of 1.6 percentage points. Patients receiving BYDUREON, Actos and metformin treatment achieved an average A1C of less than 7 percent by study end.

Treatment with BYDUREON produced an average weight loss of 4.5 pounds, which was statistically significantly greater than the average 1.7 pounds patients lost with Januvia and the average 3.3 pounds patients gained with Actos. Patients receiving metformin experienced an average weight loss of 4.4 pounds.

"The majority of patients in this study reached an optimal A1C goal of less than seven percent, which is the glucose control target recommended by the American Diabetes Association," said Orville G. Kolterman, M.D., senior vice president, chief medical officer, Amylin Pharmaceuticals. "DURATION-4 reinforced that continued presence of exenatide helped these recently diagnosed patients to achieve glycemic control. The combination of efficacy, tolerability, and once weekly dosing in this monotherapy setting further supports the potential role BYDUREON can play in helping patients and physicians manage type 2 diabetes."

More than 80 percent of patients in all treatment arms completed the study. There were no major hypoglycemia events in any treatment group. The most frequently reported adverse events among BYDUREON users were nausea (withdrawal rate less than 1 percent) and diarrhea; metformin, diarrhea and headache; Actos, upper respiratory tract infection, headache, hypertension and peripheral edema; and Januvia, upper respiratory tract infection and headache.

BYDUREON (pronounced by-DUR-ee-on) is the proposed brand name for exenatide once weekly. It is an investigational, extended-release medication for type 2 diabetes designed to deliver continuous therapeutic levels of exenatide in a single weekly dose. BYDUREON is a once-weekly formulation of exenatide, the active ingredient in BYETTA(R) (exenatide) injection, which has been available in the U.S. since June 2005 and is used in approximately 60 countries worldwide to improve glycemic control in adults with type 2 diabetes. BYDUREON and BYETTA belong to the glucagon-like peptide-1 (GLP-1) receptor agonist class of medications.

Study Design

The 26-week, double-blind, randomized, four-arm parallel study enrolled 820 patients who were not achieving adequate A1C control on diet and exercise. Patients had an average type 2 diabetes diagnosis of two to three years. The patients were randomized as follows: BYDUREON (2 mg, once per week) (n=248); metformin (dose escalated up to 2,500 mg/day) (n=246); Actos (dose escalated up to 45 mg/day) (n=163); and Januvia (100 mg/day) (n=163). The primary endpoint was reduction in A1C, while secondary endpoints included change in body weight along with other parameters of glucose control, cardiovascular health and patient-reported outcomes.

The companies plan to present the full data set at a major medical meeting and submit the data for publication.

About Diabetes

Diabetes affects more than 24 million people in the U.S. and an estimated 285 million adults worldwide.(i,ii) Approximately 90-95 percent of those affected have type 2 diabetes. Diabetes is the fifth leading cause of death by disease in the U.S. and costs

approximately $174 billion per year in direct and indirect medical expenses.(iii)

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.(iv) In addition, 85 percent of type 2 diabetes patients are overweight and 55 percent are considered obese.(v) Data indicate that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.(vi,vii)

About BYETTA(R) (exenatide) injection

BYETTA is the first FDA-approved GLP-1 receptor agonist 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 an injectable prescription medicine that may improve blood sugar (glucose) control in adults with type 2 diabetes mellitus, when used with a diet and exercise program. BYETTA is not insulin and should not be taken instead of insulin. BYETTA is not recommended to be taken with insulin. BYETTA is not for people with type 1 diabetes or people with diabetic ketoacidosis.

BYETTA provides sustained A1C control and low incidence of hypoglycemia when used alone or in combination with metformin or a thiazolidinedione, with potential weight loss. BYETTA is not a weight-loss product. BYETTA was approved in April 2005 and has been used by more than one million patients since its introduction. See important safety information below. Additional information about BYETTA is available at www.BYETTA.com.

Important Safety Information for BYETTA(R) (exenatide) injection

Based on post-marketing data, BYETTA has been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. The risk for getting low blood sugar is higher if BYETTA is taken with another medicine that can cause low blood sugar, such as a sulfonylurea. BYETTA should not be used in people who have severe kidney problems, and should be used with caution in people who have had a kidney transplant. Patients should talk with their healthcare provider if they have severe problems with their stomach, such as delayed emptying of the stomach (gastroparesis) or problems with digesting food. Severe allergic reactions can happen with BYETTA.

The most common side effects with BYETTA include nausea, vomiting, diarrhea, dizziness, headache, feeling jittery, and acid stomach. Nausea most commonly happens when first starting BYETTA, but may become less over time.

These are not all the side effects from use of BYETTA. A healthcare provider should be consulted about any side effect that is bothersome or does not go away.

For additional important safety information about BYETTA, please see the full Prescribing Information (www.byetta.com/pi) and Medication Guide (www.byetta.com/mg).

About Amylin, Lilly and Alkermes

Amylin, Lilly and Alkermes are working together to develop BYDUREON, a subcutaneous injection of exenatide for the treatment of type 2 diabetes based on Alkermes' proprietary Medisorb(R) technology for long-acting medications. BYDUREON is not currently approved by any regulatory agencies.

Amylin Pharmaceuticals is a biopharmaceutical company dedicated to improving lives of patients through the discovery, development and commercialization of innovative medicines. 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.

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 healthcare professionals improve the lives of people with diabetes, and research continues on innovative medicines to address the unmet needs of patients.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of 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.

Alkermes, Inc. is a fully integrated biotechnology company committed to developing innovative medicines to improve patients'

lives. Alkermes' robust pipeline includes extended-release injectable and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Waltham, Massachusetts, Alkermes has a research facility in Massachusetts and a commercial manufacturing facility in Ohio.

This press release contains forward-looking statements about Amylin, Lilly and Alkermes. 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 BYDUREON may not be approved by the FDA in a timely manner or at all; the companies' response to the complete response letter may not satisfy the FDA; the FDA may request additional information prior to approval; BYETTA and/or the approval of BYDUREON and the revenues generated from these products may be affected by competition; unexpected new data; safety and technical issues; clinical trials not being completed in a timely manner, not confirming previous results, not being predictive of real world use or not achieving the intended clinical endpoints; label expansion requests or NDA filings, such as the NDA filing for BYDUREON, not receiving regulatory approval; the commercial launch of BYDUREON being delayed; or manufacturing and supply issues. The potential for BYETTA and/or BYDUREON, if approved, 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 development and commercialization of pharmaceutical products including those inherent in the collaboration with and dependence upon Amylin, Lilly and/or Alkermes. These and additional risks and uncertainties are described more fully in Amylin's, Lilly's and Alkermes' most recent SEC filings including their Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K. Amylin, Lilly and Alkermes undertake no duty to update these forward-looking statements.

*BYDUREON(TM) and BYETTA**(R)** are trademarks of Amylin Pharmaceuticals, Inc., and Medisorb**(R)** is a registered trademark of Alkermes, Inc. All other marks are the marks of their respective owners.*

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(i) The International Diabetes Federation Diabetes Atlas. Available at: http://www.diabetesatlas.org/content/some-285-million-people-worldwide-will-live-diabetes-2010. Accessed May 28, 2010.

(ii) Diabetes Statistics. American Diabetes Association. Available at: http://www.diabetes.org/diabetes-basics/diabetes-statistics/. Accessed May 28, 2010.

(iii) Direct and Indirect Costs of Diabetes in the United States. American Diabetes Association. Available at: http://www.diabetes.org/how-to-help/action/resources/cost-of-diabetes.html. Accessed May 28, 2010.

(iv) Saydah SH, Fradkin J and Cowie CC. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. *JAMA*. 2004;291:335-42.

(v) Bays HE, Chapman RH, Grandy S. The relationship of body mass index to diabetes mellitus, hypertension and dyslipidaemia: comparison of data from two national surveys. *Int J Clin Pract*. 2007;61:737-47.

(vi) Nutrition Recommendations and Interventions for Diabetes: a position statement of the American Diabetes Association. *Diabetes Care*. 2007;30 Suppl 1:S48-65.

(vii) Anderson JW, Kendall CW, Jenkins DJ. Importance of weight management in type 2 diabetes: review with meta-analysis of clinical studies. *J Am Coll Nutr*. 2003;22:331-9.

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