



BYDUREON™ Safety and Tolerability Pooled Summary Data Presented at ADA 2010

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ORLANDO, Fla., June 26, 2010 /PRNewswire-FirstCall/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced results of an analysis of pooled safety data from three completed randomized controlled trials that showed the investigational product BYDUREON™ (exenatide extended-release for injectable suspension), dosed once weekly, was generally well-tolerated with a low discontinuation rate due to serious adverse events similar to pooled comparators in patients with type 2 diabetes. These findings were presented at the 70th Annual Scientific Sessions of the American Diabetes Association (ADA) in Orlando, Fla.

Safety data from the DURATION-1, -2 and -3 trials involving patients on either BYDUREON or pooled data from comparator groups including Januvia® (sitagliptin), Actos® (pioglitazone HCl) or Lantus® (insulin glargine) were analyzed. The overall incidence rates of adverse events (AEs), serious AEs and discontinuations due to serious AEs were similar for BYDUREON versus pooled comparators. AEs occurred in 77 percent of patients receiving BYDUREON versus 71 percent for pooled comparators; serious AEs were 4 percent for BYDUREON versus 5 percent for pooled comparators; and discontinuations due to serious AEs were less than 1 percent for both groups. Discontinuation for nausea was similar in BYDUREON (0.7 percent) and pooled comparator (0.5 percent) cohorts. Hypoglycemic events were lower with BYDUREON, and composite exposure-adjusted incidence rates were similar for BYDUREON versus pooled comparators for pancreatitis, gall-bladder AEs, renal impairment/dehydration and thyroid-neoplasm AEs.

In the DURATION-1, -2 and -3 studies there were no reports of severe hypersensitivity reactions, such as serious skin reactions or anaphylaxis. These data further support the known safety profile of the exenatide molecule and are consistent with the previously reported profiles of BYDUREON and BYETTA® (exenatide) injection.

"The DURATION trials not only help us understand the potential of BYDUREON in improving blood glucose control as measured by A1C, but also its safety and tolerability," said Orville G. Kolterman, M.D., senior vice president, chief medical officer, Amylin Pharmaceuticals. "Overall, these data showed that BYDUREON was generally well-tolerated with a low discontinuation rate due to serious adverse events, adding to the potential of BYDUREON as a desirable treatment option for type 2 diabetes in just one dose per week."

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, which has been available in the U.S. since June 2005 and is used in more than 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 and Findings

This analysis of the DURATION-1, -2 and -3 trials included 1,095 patients followed for 26 to 30 weeks on either BYDUREON (n=541) or pooled comparators (Januvia, Actos and Lantus; n=554). Selected analyses compared the BYDUREON cohort to patients receiving BYETTA in the DURATION-1 trial (n=145). Baseline demographics of cohorts were similar and were approximately 50 percent male; mean age 52-58 years; mean A1C 8.3-8.5 percent; and mean BMI 32-35 kg/m².

Common treatment-emergent AEs (greater-than or equal to 5 percent) that differed between BYDUREON and pooled comparator cohorts were injection-site pruritis and gastrointestinal (GI), including nausea, vomiting, diarrhea and constipation. The comparator-corrected incidence of nausea was 15 percent for BYDUREON. After three months, at which point a steady-state level of exenatide is reached, approximately 1 percent of subjects treated with BYDUREON reported new nausea. Other GI AEs included dyspepsia/reflux symptoms. Abdominal discomfort (2 percent) also was seen in BYDUREON and pooled comparator cohorts.

To further understand differences in the tolerability profile of BYDUREON and BYETTA, the incidence of GI adverse events for the BYDUREON cohort was compared to that of BYETTA. Nausea was reported more often by BYETTA recipients (35 percent) than BYDUREON recipients (20 percent). Similarly, vomiting was reported by 19 percent of BYETTA recipients compared with 8 percent of BYDUREON recipients.

Local injection-site pruritis (itchiness) (7 percent) and erythema (redness) (4 percent) were also observed with BYDUREON. The incidence of mild to moderate hypoglycemic events observed with BYDUREON treatment (16 percent) was lower compared to the pooled comparator cohort (22 percent). There were no events of major hypoglycemia. One death unrelated to assigned treatment was observed in each group. Composite exposure-adjusted cases (per 100 patient-years) were similar for BYDUREON versus pooled comparator, respectively, for pancreatitis (0.4 vs. 0.8), gall-bladder AEs (0.8 vs. 2.0), renal impairment/dehydration (1.2 vs. 1.2) and thyroid-neoplasm AEs (0.4 vs. 0.4).

About Diabetes

Diabetes affects more than 24 million people in the U.S. and an estimated 285 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 U.S. and costs approximately \$174 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 In addition, 85 percent of type 2 diabetes patients are overweight and 55 percent are considered obese.⁵ Data indicate that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.^{6,7}

About BYETTA® (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® (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® 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; the tolerability analysis mentioned in this press release not being predictive of real-world results; 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™ and BYETTA® are trademarks of Amylin Pharmaceuticals, Inc., and Medisorb® is a registered trademark of Alkermes, Inc. All other marks are the marks of their respective owners.

¹ The International Diabetes Federation Diabetes Atlas. Available at: <http://www.diabetesatlas.org/content/some-285-million-people-worldwide-will-live-diabetes-2010>. Accessed June 19, 2010.

² Diabetes Statistics. American Diabetes Association. Available at: <http://www.diabetes.org/diabetes-basics/diabetes-statistics/>. Accessed June 19, 2010.

³ 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 June 19, 2010.

⁴ 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.

⁵ Bays HE, Chapman RH and 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.

⁶ 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 and 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.

SOURCE: Alkermes

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