



## **BYETTA® and BYDUREON® to be Featured in More Than a Dozen Study Presentations at EASD 2010**

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Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced that the latest research findings on BYETTA® (exenatide) injection and the investigational product BYDUREON™ (exenatide extended-release for injectable suspension) will be presented at the 46th Annual Meeting of the European Association for the Study of Diabetes (EASD). The EASD annual meeting, taking place from Sept. 20-24 in Stockholm, Sweden, brings together more than 16,000 attendees and is an important platform in Europe for professional exchange in the diabetes field.

"At this year's EASD, we are pleased to share data that deepen our understanding of the safety and efficacy of BYETTA, as well as the potential benefits of BYDUREON," stated Orville G. Kolterman, M.D., senior vice president, chief medical officer, Amylin Pharmaceuticals. "These studies underscore our commitment to advancing diabetes treatment."

Key BYETTA and BYDUREON abstracts for EASD 2010 include:

- Oral: Presentation #73, Sept. 22, 10:45 a.m.-12:15 p.m. CEST  
"Exenatide Added to Insulin Glargine-Treated Patients with Type 2 Diabetes Provided Excellent Fasting and Postprandial Control with Weight Loss and no Increased Risk of Hypoglycaemia" will be presented by Richard Bergenstal, M.D., International Diabetes Center, Minneapolis
- Poster: Presentation #833, Sept. 21, 1:30-2:30 p.m. CEST  
"Exenatide Added to a Thiazolidinedione with or without Metformin Resulted in Superior Glycaemic Control Versus Placebo after 26 Weeks of Treatment" will be presented by Joanne Liutkus, M.D., Medicine Professional Corporation, Cambridge, Ontario, Canada
- Poster: Presentation #836, Sept. 21, 1:30-2:30 p.m. CEST  
"Meta-Analysis of the Efficacy of GLP-1R Agonists and DPP-4 Inhibitors for Treatment of Type 2 Diabetes Mellitus" will be presented by Vanita Aroda, M.D., MedStar Research, Hyattsville, Md.
- Poster: Presentation #837, Sept. 21, 1:30-2:30 p.m. CEST  
"Risk of Cardiovascular Events in Patients with Type 2 Diabetes Treated with Exenatide or Other Glucose-Lowering Therapies: A Retrospective Analysis of the LifeLink™ Database" will be presented by Jennie Best, Ph.D., Amylin
- Poster: Presentation #842, Sept. 22, 12:30-1:30 p.m. CEST  
"DURATION-2: Effect of Switching to Once-Weekly Exenatide from Maximum Daily Doses of Sitagliptin or Pioglitazone" will be presented by Carol H. Wysham, M.D., Rockwood Clinic, Spokane, Wash.
- Poster: Presentation #858, Sept. 23, 12:30-1:30 p.m. CEST  
"Antibodies to Exenatide did not Cross-React with Human GLP-1 or Glucagon or Alter the Efficacy or Safety of Exenatide" will be presented by Mark Fineman, Amylin
- Poster: Presentation #863, Sept. 23, 1:30-2:30 p.m. CEST  
"Impact of Exenatide Once Weekly and Insulin Glargine on Glucose Control and Cardiovascular Risk Factors in Subjects with Type 2 Diabetes" will be presented by Michaela Diamant, M.D., Diabetes Centre, VU University Medical Centre, Amsterdam

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. BYETTA 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.

## About Diabetes

Diabetes affects an estimated 285 million adults worldwide and more than 24 million people in the U.S.(1,2) Approximately 90-95 percent of those affected have type 2 diabetes. Diabetes costs approximately \$174 billion per year in direct and indirect medical expenses in the U.S.(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 1.3 million patients since its introduction. See important safety information below. Additional information about BYETTA is available at <http://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 (<http://pi.lilly.com/us/byetta-pi.pdf>) and Medication Guide (<http://pi.lilly.com/us/byetta-ppi.pdf>).**

## 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.

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, 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, Mass., 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 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.

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- (1) The International Diabetes Federation Diabetes Atlas. Available at: <http://www.diabetesatlas.org/content/some-285-million-people-worldwide-will-live-diabetes-2010>. Accessed September 10, 2010.
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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*. 2004;291:335-42.
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SOURCE Amylin Pharmaceuticals, Inc.