



Alkermes Announces Amylin and Lilly Will Present More than 20 Studies for Exenatide at EASD 2009

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SAN DIEGO & INDIANAPOLIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 24, 2009-- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) will unveil data from more than 20 studies at the 45th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Vienna, Austria, taking place from Sept. 29 to Oct. 2. The companies will present the latest research findings on BYETTA® (exenatide) injection and exenatide once weekly. The EASD annual meeting, which brings together more than 14,000 delegates, is the most important platform in Europe for professional exchange in the diabetes field.

"The presentations at EASD continue to reinforce the efficacy and safety of BYETTA and the promise of exenatide once weekly as a potential new treatment option for patients with type 2 diabetes," stated Orville G. Kolterman, M.D., senior vice president of research and development, Amylin Pharmaceuticals. "EASD is a venue where researchers and clinical practitioners from around the world gather to discuss new developments in diabetes care. We look forward to participating in this exchange of ideas by presenting compelling data on the exenatide molecule."

Key exenatide abstracts for EASD 2009 include:

Clinical Trial Data

- **Poster: Presentation #729, Sept. 30, 1:45-2:45 p.m. CEST**
"Effects of Exenatide plus Rosiglitazone on Measures of Beta Cell Function and Insulin Sensitivity in Subjects with Type 2 Diabetes Previously Treated With Metformin" will be presented by Leonard Glass, M.D.
- **Poster: Presentation #730, Sept. 30, 1:45-2:45 p.m. CEST**
"Exenatide Once Weekly Treatment Elicits Sustained Glycaemic Control and Weight Loss Over 2 Years" will be presented by Michael Trautmann, M.D.
- **Poster: Presentation #739, Oct. 1, 12:45-1:45 p.m. CEST**
"DURATION-2: Exenatide Once Weekly Demonstrated Superior Glycemic Control and Weight Reduction Compared to Sitagliptin or Pioglitazone After 26 Weeks of Treatment" will be presented by Carol Wysham, M.D.
- **Poster: Presentation #795, Oct. 1, 12:45-1:45 p.m. CEST**
"Changes in Adipokines in Type 2 Diabetic Patients Treated with Exenatide versus Glimepiride on Metformin Background – Results of a Prospective, Randomized Controlled Study Over 9 Months" will be presented by Baptist Gallwitz, M.D.

Safety Assessments

- **Oral: Presentation #6, Sept. 30, 12:15-12:30 p.m. CEST**
"Incidence of Acute Pancreatitis in Exenatide Initiators Compared to Other Antidiabetic Drug Initiators: A Retrospective, Cohort Study" will be presented by Gary Bloomgren, M.D.
- **Poster: Presentation #758, Oct. 2, 12:45-1:45 p.m. CEST**
"Exenatide Once Weekly Improved Cardiometabolic Risk Factors in Subjects with Type 2 Diabetes During One Year of Treatment" will be presented by Richard Bergenstal, M.D.
- **Poster: Presentation #759, Oct. 2, 12:45-1:45 p.m. CEST**
"Cardiovascular Safety of Exenatide BID: An Integrated-Analysis from Long-Term Controlled Clinical Trials in Subjects with Type 2 Diabetes" will be presented by Larry Shen, Ph.D.
- **Poster: Presentation #768, Oct. 2, 1:45-2:45 p.m. CEST**
"Safety and Tolerability of Exenatide BID in Patients With Type 2 Diabetes: Integrated Analysis of 3854 Patients From 11 Comparator Controlled Clinical Trials" will be presented by Matthew Wintle, M.D.

Patient-Reported Outcomes

- **Poster: Abstract Presentation #745, Oct. 1, 12:45-1:45 p.m. CEST**
"DURATION 2: Weight-Related Quality of Life, Psychological Well-Being, and Satisfaction with Exenatide Once Weekly Compared to Sitagliptin or Pioglitazone After 26 Weeks of Treatment" will be presented by Jennie Best, Ph.D.

About BYETTA® (exenatide) Injection

BYETTA is the first and only FDA-approved incretin mimetic 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 and low incidence of hypoglycemia when used 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 million patients since its introduction. For full prescribing information, visit www.BYETTA.com.

Important Safety Information for BYETTA

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, hypoglycemia (low blood sugar) 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 the most common side effect 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 of 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 full prescribing information, visit www.BYETTA.com.

About Diabetes

Diabetes affects approximately 24 million people in the U.S. and an estimated 246 million adults worldwide.(i,ii) Approximately 90-95 percent of affected adults have type 2 diabetes. Diabetes is the fifth leading cause of death by disease in the U.S. and results in 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 Amylin, Lilly and Alkermes

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

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® (pramlintide acetate) injection and BYETTA® (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. Further information on 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 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, pulmonary and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Cambridge, Massachusetts, Alkermes has research facilities in Massachusetts and a commercial manufacturing facility in Ohio.

This press release contains forward-looking statements about Amylin, Lilly and Alkermes, BYETTA and the investigational drug, exenatide once weekly. 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/or exenatide once weekly may be affected by unexpected new data; safety and technical issues; clinical trials not being completed in a timely manner, not confirming previous results, not being predictive of future results, or not achieving the intended clinical endpoints; label expansion requests not being submitted in a timely manner; regulatory approval, including approval for exenatide once weekly, being delayed or not being received; or manufacturing and supply issues. The potential for BYETTA and/or exenatide once weekly 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 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.

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(i) "All About Diabetes." American Diabetes Association. Available at: <http://www.diabetes.org/about-diabetes.jsp>. Accessed July 13, 2009.

(ii) The International Diabetes Federation Diabetes Atlas. Available at: <http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A>. Accessed July 13, 2009.

(iii) "Direct and Indirect Costs of Diabetes in the United States." American Diabetes Association. Available at: <http://www.diabetes.org/diabetes-statistics/cost-of-diabetes-in-us.jsp>. Accessed July 13, 2009.

(iv) 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.

(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*. 2008;31 Suppl 1:S61-78.

(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.

Source: Alkermes, Inc.

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