



Amylin Pharmaceuticals and Eli Lilly Provide Context for FDA Alert for BYETTA

SAN DIEGO and INDIANAPOLIS, Aug 26, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) and Eli Lilly and Company (NYSE: LLY) in a conference call today provided context and additional information regarding the August 18, 2008 U.S. Food and Drug Administration (FDA) update to a prior alert for BYETTA[®] (exenatide) injection referencing pancreatitis. The companies were aware of the pancreatitis cases referenced in the alert, as well as others, and previously reported these cases to the FDA. The complete conference call replay will be available through Amylin's and Lilly's corporate websites after the call.

Since 2006, the U.S. prescribing information for BYETTA has included information about pancreatitis. A recent study has also shown that patients with type 2 diabetes were at nearly three times the risk of developing pancreatitis than those without diabetes.(1) While a definite causal relationship between BYETTA and pancreatitis has not been proved, to better understand the suspected relationship, Amylin and Lilly continue to pursue a comprehensive drug safety program that includes extensive internal and external review of individual cases, and clinical and epidemiologic studies.

"At Amylin and Lilly, patient safety is our foremost concern. We are committed to continuing to work closely with the FDA to ensure that physicians and patients are provided with accurate information about any potential risks associated with the use of our products," said Orville G. Kolterman, Senior Vice President, Research and Development at Amylin. "It is important to understand that pancreatitis, an inflammatory condition of the pancreas, is a rare event. Further, the characteristics and complications of the pancreatitis cases in patients on BYETTA are consistent with pancreatitis in the general population. We believe BYETTA continues to have a positive benefit-risk profile for patients with type 2 diabetes."

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, low incidence of hypoglycemia when used with metformin or a thiazolidinedione, and progressive weight loss. BYETTA was approved in April 2005 and has been used by approximately one million patients since its introduction. For full prescribing information, visit www.BYETTA.com.

About Diabetes

Diabetes affects more than 21 million in the United States and an estimated 246 million adults worldwide.(2,3) 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.(4)

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.(5) In addition, 85 percent of type 2 diabetes patients are overweight and 55 percent are considered obese.(6) Data support that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.(7,8)

Important Safety Information for BYETTA

BYETTA improves glucose (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, 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 Amylin and Lilly

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 with over 2,000 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 healthcare 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.

This press release contains forward-looking statements about Amylin and Lilly. 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 the revenues generated from BYETTA may be affected by competition; unexpected new data; safety and technical issues; clinical trials not confirming previous results; pre-clinical trials not predicting future results; label expansion requests not being submitted in a timely manner or receiving regulatory approval; or manufacturing and supply issues. The potential for BYETTA 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 commercialization of pharmaceutical products. These and additional risks and uncertainties are described more fully in Amylin's and Lilly's most recently filed SEC including their Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K. Amylin and Lilly undertake no duty to update these forward-looking statements.

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3. "All About Diabetes." American Diabetes Association. Available at: <http://www.diabetes.org/about-diabetes.jsp>. Accessed June 6, 2008.

4. "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 June 6, 2008.

5. 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.

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

8. 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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