



## **Study Finds BYETTA(R) Use Was Not Associated With Increased Rate of Acute Pancreatitis Compared to Other Antidiabetic Drugs: Final Results Presented at ADA 2010**

### **Chart Review Consistent with Earlier Related Claims Data Analysis of More Than 25,000 BYETTA Patients Accrued Over Three Years**

ORLANDO, Fla., June 26, 2010 /PRNewswire via COMTEX News Network/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) and Eli Lilly and Company (NYSE: LLY) today announced final results from a retrospective study including more than 260,000 patients that showed the risk of acute pancreatitis among initiators of BYETTA(R) (exenatide) injection was not increased compared to initiators of other antidiabetic therapies. These findings were presented at the 70th Annual Scientific Sessions of the American Diabetes Association (ADA) in Orlando, Fla.

The retrospective study used data accrued over three years from a large, geographically diverse U.S. healthcare insurance claims database to examine the risk of acute pancreatitis in more than 25,000 patients who were treated with BYETTA, relative to nearly 235,000 patients who were treated with other antidiabetes medications. Medical records from claims-identified cases of acute pancreatitis were reviewed by four gastroenterologists, blinded to drug exposure, using a standard assessment tool. In a nested case-control study (NCCS) based on the review, use of BYETTA was not associated with an increased rate of acute pancreatitis compared to the other antidiabetes medications, based on the adjusted odds ratio and 95 percent confidence interval (CI) for current (0.2; CI 0.0-1.4), recent (0.1; CI 0.0-1.3) and past (1.1; CI 0.1-12.3) use of BYETTA.

"This medical records review is consistent with a related earlier analysis of claims data, which showed no evidence for a higher risk of acute pancreatitis associated with the use of BYETTA compared to other common antidiabetes therapies,"(i) said Orville G. Kolterman, M.D., senior vice president, chief medical officer, Amylin Pharmaceuticals. "The study suggested that cases of pancreatitis in past BYETTA users may be related to other risk factors, such as gall stones, past acute pancreatitis and obesity."

Amylin and Lilly are continuing work to better understand the relationship between BYETTA and pancreatitis described in some spontaneously reported cases. In keeping with the companies' focus on patient safety, Amylin and Lilly continue to pursue a drug safety program that includes thorough investigation of individual spontaneous case reports along with clinical and epidemiologic studies. Patients and healthcare professionals should refer to product labeling for guidance regarding the use of BYETTA.

### **Study Design and Findings**

Eligible patients were enrolled in the healthcare plan for at least a continuous nine-month baseline period with no history of chronic or acute pancreatitis prior to initiation of a new antidiabetic therapy. Adjudication of 652 claims-identified acute pancreatitis cases resulted in 40 confirmed acute pancreatitis cases in the BYETTA initiators and 254 confirmed cases in the other antidiabetic drug initiators. The NCCS analysis incorporated covariates (claims- and chart-derived) temporally related to acute pancreatitis occurrence to account for differences in the prevalence of risk factors between patients who persisted on or discontinued the study drugs.

### **About Diabetes**

Diabetes affects more than 24 million people in the U.S. and an estimated 285 million adults worldwide.(ii,iii) 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.(iv)

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

### **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](http://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](http://www.byetta.com/pi)) and Medication Guide ([www.byetta.com/mg](http://www.byetta.com/mg)).**

### **About Amylin and Lilly**

Amylin Pharmaceuticals is a biopharmaceutical company dedicated to improving lives of patients through the discovery, development and commercialization of innovative medicines. Amylin has developed and gained approval for two first-in-class medicines for diabetes, SYMLIN(R) (pramlintide acetate) injection and BYETTA(R) (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 [www.amylin.com](http://www.amylin.com).

Through a long-standing commitment to diabetes care, Lilly seeks to provide patients with breakthrough treatments that enable them to live longer, healthier and fuller lives. Since 1923, Lilly has been an 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](http://www.lillydiabetes.com).

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, Ind., 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](http://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/or the revenues generated from BYETTA, may be affected by competition; unexpected new data; safety and technical issues; the study results 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 not 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 development and commercialization of pharmaceutical products, including those inherent in the collaboration with and dependence upon Amylin and/or Lilly. These and additional risks and uncertainties are described more fully in Amylin's and Lilly's most recent SEC filings, 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.*

BYETTA(R) is a registered trademark of Amylin Pharmaceuticals, Inc.

## P-LLY

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