

Meta-Analysis of clinical data showed no increased risk of cardiovascular events associated with wxe

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Amylin Pharmaceuticals, Inc. and Eli Lilly and Company announced results from a meta-analysis of cardiovascular (CV) events that showed no increased risk of CV events associated with BYETTA(R) (exenatide) injection use compared to a pooled comparator group treated with either placebo or insulin. This analysis applied the principles that were described in the U.S. Food and Drug Administration's (FDA's) guidance for evaluating CV risk in type 2 diabetes agents. These findings were presented at the 69th Annual Scientific Sessions of the American Diabetes Association (ADA) in New Orleans.

In the meta-analysis of 12 completed, randomized, controlled clinical trials of 12-52 weeks, the unadjusted rate at which patients experienced at least one CV event was 2.0 percent for BYETTA and 2.6 percent for the comparator group; the relative risk between BYETTA and the comparator group was 0.69 with a 95 percent confidence interval of 0.46-1.03. "The data from this analysis are reassuring and consistent with clinical trial data that show favorable effects of exenatide on cardiovascular risk factors," said Byron Hoogwerf, M.D., clinical research physician for Eli Lilly and Company. "Amylin and Lilly intend to initiate a large cardiovascular outcomes trial to further evaluate safety and to determine if there are cardiovascular benefits of exenatide treatment." "Patient safety is of utmost concern at Amylin and Lilly," said Orville G. Kolterman, M.D., senior vice president of research and development at Amylin. "Given that people living with diabetes have two- to four-times greater risk of cardiovascular disease compared to people who don't have diabetes, we are comforted to have data that showed patients treated with BYETTA had no increased risk of cardiovascular events and that BYETTA may offer a potential cardiovascular benefit." Study Design and Findings In this integrated analysis, 2,316 BYETTA subjects and 1,629 pooled comparator subjects were treated for a total of 1,072 and 780 patient-years of exposure, respectively. The unadjusted incidence of experiencing at least one CV event was 2.0 percent for BYETTA and 2.6 percent for pooled comparator; the relative risk between BYETTA and pooled comparator was 0.69 (95 percent confidence interval: 0.46-1.03). The Exposure Adjusted Incidence Rate (expressed as per 1,000 patient years) was 43.4 for BYETTA and 54.4 for pooled comparator with a relative risk 0.80 (95 percent confidence interval: 0.53-1.21). CV events included stroke, myocardial ischemia, myocardial infarction, cardiac mortality, arrhythmia, revascularization procedures and congestive heart failure. About Diabetes Diabetes affects more than 23 million people in the U.S. and an estimated 246 million adults worldwide. (i,ii) 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 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 support that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control. (vi,vii) About BYETTA(R) (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 one million patients since its introduction. For full prescribing information, visit www.BYETTA.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, 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.