



One Year Study of Exenatide Treatment Showed Improved Beta-Cell Function

-- When compared to insulin glargine, exenatide offered added benefits of weight loss and improved beta-cell function when used with metformin --

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Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) and Eli Lilly and Company (NYSE: LLY) today announced study results comparing treatment of exenatide injection with insulin glargine on beta-cell function, glycemic control and weight in people with type 2 diabetes. Study findings showed one year of exenatide therapy, as compared to insulin glargine, markedly improved different indices of beta-cell function, along with similar glycemic improvement. In addition, patients treated with exenatide lost weight, whereas patients treated with glargine gained weight. These findings were presented at the 43rd Annual Meeting of the European Association for the Study of Diabetes (EASD) in Amsterdam, The Netherlands(1).

In this randomized study, 69 people with type 2 diabetes who were treated with exenatide (5 mcg BID for 4 weeks and 10 mcg BID to 20 mcg TID (20 mcg TID is a currently unapproved dosage of the marketed formulation of exenatide, BYETTA(R) (exenatide) injection) for the remainder of the year) or insulin glargine (both with metformin) were compared on measures of beta-cell function, blood sugar control and weight change after one year (52-weeks) of treatment.

In this study, people with type 2 diabetes who used exenatide for one year, compared to those treated with insulin glargine, showed significant improvements in beta-cell function as measured by arginine and glucose induced C-peptide (a peptide associated with insulin production) secretion during a glucose clamp procedure (a technique used to assess insulin secretion) (2,3). Specifically, C-peptide secretion in response to arginine administration (which produces maximal beta-cell stimulation) was 146 percent greater after one year of treatment with exenatide when compared to insulin glargine (mean ratio relative to baseline for exenatide and insulin glargine + or -SEM: 3.19 + or - 0.24 vs. 1.31 + or - 0.07, respectively, $p < 0.0001$). First phase glucose induced C-peptide secretion was 52 percent greater after one year of exenatide compared to insulin glargine therapy (mean ratio relative to baseline + or -SEM: 1.75 + or - 0.10 vs. 1.16 + or - 0.06, respectively, $p < 0.0001$). Second phase C-peptide secretion increased 185 percent more with exenatide (mean ratio relative to baseline + or -SEM: 3.05 + or - 0.22) versus insulin glargine (1.08 + or - 0.05, $p < 0.0001$).

The average HbA1c of randomized patients at the start of the trial was 7.5 + or - 0.1 percent. Treatment with exenatide resulted in blood sugar control (as measured by reductions in HbA1c) comparable to treatment with insulin glargine (-0.8 + or - 0.1 percent and -0.7 + or - 0.2 percent, respectively, a difference between groups that was not statistically significant).

On average, exenatide treatment also resulted in a reduction in body weight. At the start of the study, randomized patients had a mean weight of 91.4 + or - 1.6 kg (201.6 + or - 3.5 lb). Patients on exenatide lost an average of 3.6 + or - 0.6 kg (7.8 + or - 1.4 lb), while those receiving insulin glargine gained an average of 1.0 + or - 0.8 kg (2.2 + or - 1.8 lb). The total difference in weight between the exenatide and insulin glargine groups was 4.6 kg (10.0 lb).

"Previous exenatide studies have shown comparable glycemic improvements when compared to insulin glargine, as well as improved beta-cell function that has only been associated with exenatide treatment," said Michaela Diamant, M.D., Ph.D., Associate Professor of Endocrinology, Department of Endocrinology, VU University Medical Center, Amsterdam, The Netherlands, and an author of the study. "This study lends further support to past findings and showed that adding exenatide significantly improved beta-cell function as measured by both glucose and arginine induced insulin secretion."

The side effects associated with exenatide treatment were consistent with those seen in previous studies. In clinical trials, the most common side effect is nausea, most of which is mild to moderate, affecting approximately half of patients and usually decreasing over time. Exenatide-treated patients had a lower incidence of hypoglycemia compared to insulin glargine-treated patients (8.3 percent vs. 24.2 percent, respectively).

About BYETTA(R) (exenatide) injection

BYETTA is the first in a class of drugs called incretin mimetics 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 U.S.

Food and Drug Administration ("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. For full prescribing information, visit www.BYETTA.com.

About Incretin Mimetics

Incretin mimetics are a distinct class of agents used to treat diabetes. An incretin mimetic works to mimic the anti-diabetic or glucose-lowering actions of naturally occurring human hormones called incretins. These actions include stimulating the body's ability to produce insulin in response to elevated levels of blood sugar, inhibiting the release of a hormone called glucagon following meals, slowing the rate at which nutrients are absorbed into the bloodstream and reducing food intake.

About Diabetes

Diabetes affects more than 20 million in the United States and an estimated 246 million adults worldwide(4,5). 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(6).

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(7).

Important Safety Information for BYETTA(R) (exenatide) injection

BYETTA improves glucose (blood sugar) control in patients with type 2 diabetes who are taking 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 with the stomach or food digestion, or those who have severe kidney disease. Before using BYETTA, patients should tell their healthcare provider if they are pregnant, plan to become pregnant, or are breastfeeding. BYETTA has not been studied in children.

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 most common when first starting BYETTA, but decreases over time in most patients. BYETTA may reduce appetite, the amount of food eaten, and body weight. These are not all the side effects with BYETTA. A healthcare provider should be consulted about any side effect that is bothersome or does not go away.

For complete safety profile and other important prescribing considerations, 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. Amylin's research and development activities leverage the company's expertise in metabolism to develop potential therapies to treat diabetes and obesity. Amylin is located in San Diego, California with over 1,700 employees nationwide.

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 health care 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 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.

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 exenatide and the revenues generated from exenatide may be affected by competition, unexpected new data, technical issues, clinical trials not confirming previous results or 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 exenatide 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 and Lilly's most recently filed United States Securities Exchange Commission documents such as their Quarterly Reports on Form 10-Q. Amylin and Lilly undertake no duty to update these forward-looking

statements.

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