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Lilly's Basal Insulin Peglispro Shows Superiority in HbA1c Reduction Compared to Insulin Glargine in Three Phase III Trials in Patients with Type 2 Diabetes

Lilly expects U.S. and European regulatory submissions by Q1 2015

INDIANAPOLIS, May 12, 2014 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced positive top-line results of three completed Phase III clinical trials in patients with type 2 diabetes for basal insulin peglispro (BIL), which is being studied as a once-daily treatment for both type 1 and type 2 diabetes. The primary efficacy endpoint of non-inferior reduction in hemoglobin A1c (HbA1c) compared to insulin glargine was met in all three trials. Having met the primary endpoints, superiority for HbA1c lowering was examined and, in all three trials, BIL showed a statistically superior reduction in HbA1c compared with insulin glargine.

The clinical trials evaluated three specific populations of patients with type 2 diabetes: those who were not previously taking insulin (IMAGINE-2); those taking basal insulin with mealtime insulin (IMAGINE-4); and those currently taking a basal insulin (IMAGINE-5). All three clinical trials compared BIL, an investigational basal insulin, with insulin glargine.

"These results are promising. Basal insulin peglispro is the first basal insulin to demonstrate consistently superior HbA1c reduction versus insulin glargine in Phase III clinical trials," said Enrique Conterno, president, Lilly Diabetes. "If approved, BIL could offer a differentiated profile and provide an important new treatment option for patients with diabetes. We are on track to make regulatory filings by Q1 next year."

These clinical studies also evaluated the secondary endpoints of nocturnal hypoglycemia rates and changes in weight. In all three clinical trials, patients taking BIL experienced statistically significant lower rates of nocturnal hypoglycemia than those taking insulin glargine. In addition, patients taking BIL had comparable to statistically significant less weight gain.

"In patients with type 2 diabetes taking insulin glargine, nocturnal hypoglycemia and weight gain may be barriers to improving glycemic control. The fact that patients treated with BIL had lower rates of nocturnal hypoglycemia and comparable to less weight gain while achieving superior improvements in glycemic control is noteworthy," said David Kendall, M.D., distinguished medical fellow, Lilly Diabetes.

Additional Safety Results
The additional safety findings in these Phase III clinical trials were generally consistent with findings reported in the BIL Phase II clinical trial in patients with type 2 diabetes.

In all three clinical trials, patients taking BIL had a small but statistically significant increase in triglycerides. In IMAGINE-4 and IMAGINE-5, there was a corresponding small but statistically significant reduction in HDL (high-density lipoprotein) cholesterol compared with those taking insulin glargine; this was not observed in IMAGINE-2. In IMAGINE-2 and IMAGINE-4, changes in LDL (low-density lipoprotein) cholesterol were not significantly different in patients taking BIL compared with those taking insulin glargine. In IMAGINE-5, LDL significantly decreased at 52 weeks in BIL-treated patients compared with those taking insulin glargine. In an analysis across clinical trials completed to date in patients with type 2 diabetes, the rates of adverse cardiovascular events among patients taking BIL and those taking insulin glargine were similar, with the upper limit of the 95 percent confidence interval below 1.8.

In all three clinical trials, more patients taking BIL had an increase in the liver enzyme ALT (alanine aminotransferase) to greater than three times the upper limit of the normal range compared with those taking insulin glargine. No cases of severe drug-induced liver injury (Hy's Law) occurred in these studies. In IMAGINE-2 and IMAGINE-5, liver fat was measured using MRI imaging in a subset of patients. In the clinical trial of insulin-naive patients with type 2 diabetes (IMAGINE-2), liver fat in patients treated with BIL did not change from baseline while patients taking insulin glargine experienced a decrease in liver fat from baseline. In the clinical trial of patients with type 2 diabetes who were already taking a basal insulin (IMAGINE-5), patients taking BIL experienced an increase in liver fat from baseline that stabilized after 26 weeks. Liver fat levels did not change in patients taking insulin glargine during the study.

Data Disclosure Plans and Regulatory Submission
Top-line results for the Phase III clinical trials of patients with type 1 diabetes are planned for release by the end of Q3 this year at the time when both Phase III clinical trials are complete.

Detailed study results for Phase III type 1 and type 2 diabetes clinical trials are expected to be disclosed at major medical conferences in 2015. At an upcoming medical meeting in 2014, Lilly will present new data regarding BIL's mechanism of action.

Based on Phase III clinical trial results to date, Lilly expects to submit BIL for regulatory review to the U.S. Food and Drug Administration and the European Medicines Agency by the end of Q1 2015.

About the IMAGINE Clinical Trials
IMAGINE-2 is a Phase III randomized 52-week double-blind study of BIL (n=1,003) compared to insulin glargine (n=535) in insulin-naive patients with type 2 diabetes. The study insulin therapy was taken alone or on a background of oral antihyperglycemic medication. A subset of patients is continuing in this study until 78 weeks of treatment.

IMAGINE-4 is a Phase III 26-week randomized double-blind study designed to compare BIL (n=691) with insulin glargine (n=678) in combination with mealtime insulin in patients with type 2 diabetes.

IMAGINE-5 is a Phase III 52-week open-label study designed to evaluate BIL (n=307) compared to insulin glargine (n=159) in patients with type 2 diabetes already taking a basal insulin. The study insulin was administered alone or in combination with oral antihyperglycemic medications.

About Basal Insulin Peglispro
Basal insulin peglispro, which was discovered and developed in Lilly Research Laboratories, is currently in Phase III clinical trials and is among several diabetes molecules in the Lilly late-stage pipeline. BIL is an investigational basal insulin being studied as a once-daily treatment for type 1 and type 2 diabetes.

About Lilly Diabetes
Lilly has been a global leader in diabetes care since 1923, when we introduced the world's first commercial insulin. Today we are building upon this heritage by working to meet the diverse needs of people with diabetes and those who care for them. Through research and collaboration, a broad and growing product portfolio and a continued determination to provide real solutions—from medicines to support programs and more—we strive to make life better for all those affected by diabetes around the world. For more information, visit www.lillydiabetes.com.

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and http://newsroom.lilly.com/social-channels.

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This press release contains forward-looking statements about an investigational compound basal insulin peglispro, which is currently in development for the treatment of diabetes. It reflects Lilly's current beliefs; however, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that basal insulin peglispro will receive required regulatory approvals or prove to be commercially successful. For further discussion of these and other risks and uncertainties, please see Lilly's latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

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