October 22, 2012

Lilly Diabetes Announces Positive Results of Phase III Trials of Dulaglutide in Type 2 Diabetes

Company Shares Top-line Results on Three Completed AWARD Trials

INDIANAPOLIS, Oct. 22, 2012 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced positive top-line results of three completed Phase III AWARD trials for dulaglutide, an investigational, long-acting glucagon-like peptide 1 (GLP-1) analog being studied as a once-weekly treatment for type 2 diabetes. Primary efficacy endpoints, as measured by reduction in hemoglobin A1c (HbA1c) at the 1.5 mg dose, were met in three studies (AWARD-1, AWARD-3 and AWARD-5). Having met the primary endpoints, superiority for HbA1c lowering was examined, and both doses of dulaglutide (0.75mg and 1.5mg) demonstrated statistically superior reduction in HbA1c from baseline compared to: exenatide twice-daily injection at 26 weeks (AWARD-1); metformin at 26 weeks (AWARD-3); and sitagliptin at 52 weeks (AWARD-5).

Across the three completed AWARD studies, the most frequently reported adverse events were gastrointestinal-related. These adverse event findings are consistent with prior studies of dulaglutide.

There are a number of additional AWARD (Assessment of Weekly AdministRation of LY2189265 in Diabetes) trials ongoing. Two of these studies for submission, AWARD-2 and AWARD-4, will conclude in the next few months.

"We're very encouraged by the results to date from our Phase III dulaglutide trials and are pleased to be one step closer to offering a new GLP-1 treatment option for type 2 diabetes," said Enrique Conterno, President, Lilly Diabetes. "People with diabetes require different treatment options based on their individual needs. That's why Lilly Diabetes is committed to delivering a broad, comprehensive portfolio of therapies."

Lilly plans to present detailed data from the AWARD studies at scientific meetings in 2013 and 2014. The company expects to submit dulaglutide to regulatory authorities during 2013 with the timing of regulatory submission in the United States dependent upon satisfactory completion of U.S. Food and Drug Administration requirements for assessment of cardiovascular risk.

About the AWARD (Assessment of Weekly AdministRation of LY2189265 in Diabetes) studies planned to support registration filings.

AWARD-1 was a randomized, 52-week, placebo-controlled comparison of the effects of dulaglutide and exenatide on glycemic control in patients with type 2 diabetes on metformin and pioglitazone. The primary objective of the study, conducted in 978 patients, was to evaluate whether dulaglutide 1.5mg, dosed once-weekly, was superior to placebo in reducing HbA1c from baseline at 26 weeks.

AWARD-2 is an ongoing randomized, 78-week, open-label comparison of the effects of dulaglutide and insulin glargine on glycemic control in patients with type 2 diabetes on metformin and glimepiride. The primary objective of the study is to evaluate whether dulaglutide 1.5 mg, dosed once-weekly, is non-inferior to insulin glargine in reducing HbA1c from baseline at 52 weeks. Superiority testing will be performed if the statistical criterion for non-inferiority is satisfied.

AWARD-3 was a randomized, 52-week, double-blind comparison of the effects of dulaglutide and metformin on glycemic control in patients with early type 2 diabetes. The primary objective of the study, conducted in 807 patients, was to evaluate whether dulaglutide 1.5 mg, dosed once-weekly, was non-inferior to metformin in reducing HbA1c from baseline at 26 weeks. Superiority testing was performed as the statistical criterion for non-inferiority was satisfied.

AWARD-4 is an ongoing randomized, 52-week, open-label comparison of the effects of dulaglutide and insulin glargine, both in combination with insulin lispro, in patients with type 2 diabetes. The primary objective of the study is to evaluate whether dulaglutide 1.5 mg, dosed once-weekly, is non-inferior to insulin glargine in reducing HbA1c from baseline at 26 weeks. Superiority testing will be performed if the statistical criterion for non-inferiority is satisfied.

AWARD-5 was a randomized, 104 week, double-blind, placebo-controlled comparison of the effects of dulaglutide and sitagliptin on glycemic control in patients with type 2 diabetes on metformin. The primary objective of the study, conducted in 1,098 patients, was to evaluate whether dulaglutide 1.5 mg, dosed once-weekly, was non-inferior to sitagliptin in reducing HbA1c from baseline at 52 weeks. Superiority testing was performed as the statistical criterion for non-inferiority was satisfied.

About Diabetes

Approximately 25.8 million Americans[1] and an estimated 366 million people[2] worldwide have type 1 and type 2 diabetes. Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diabetes cases. Diabetes is a chronic disease that occurs when the body either does not properly produce, or use, the hormone insulin.[3]

About Lilly Diabetes

Lilly has been a global leader in diabetes care since 1923, when Lilly introduced the world's first commercial insulin. Today Lilly works to meet the diverse needs of people with diabetes through research and collaboration, a broad and growing product portfolio and a continued commitment to providing real solutions — from medicines to support programs and more — to make lives better. For more information, visit www.lillydiabetes.com**.**

About Eli Lilly and Company (NYSE: LLY)

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. P-LLY

This press release contains forward-looking statements about dulaglutide that are based on Lilly's current expectations. Actual results could differ materially from these expectations. There are significant risks and uncertainties in the process of drug development and commercialization. There can be no guarantee that future study results and patient experience will be consistent with the study findings to date. There can also be no guarantee that dulaglutide will be submitted to regulatory authorities in 2013, that it will receive the necessary clinical and manufacturing regulatory approvals, or that it will prove to be commercially successful. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, please see the company's latest Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. Except as required by law, the company undertakes no duty to update forward-looking statements.

[1] Centers for Disease Control. National Diabetes Fact Sheet-2011. Available at: http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf. Accessed on: February 22, 2012.

[2] International Diabetes Federation. Diabetes Atlas, 5th Edition: Fact Sheet. 2011.

[3] International Diabetes Federation. Diabetes Atlas, 5th Edition: What is Diabetes? http://www.idf.org/diabetesatlas/5e/what-is-diabetes. Accessed on: February 22, 2012.

(Logo: http://photos.prnewswire.com/prnh/20031219/LLYLOGO)

SOURCE Eli Lilly and Company