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Lilly's Investigational GLP-1 Receptor Agonist, Dulaglutide, Showed Superior Glycemic Control Versus Comparators in Patients with Type 2 Diabetes

Safety and Efficacy Results from Three Phase III Registration Clinical Trials Presented at the 73rd American Diabetes Association Scientific Sessions®

CHICAGO, June 22, 2013 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced detailed safety and efficacy results from three Phase III AWARD trials for dulaglutide, an investigational, long-acting glucagon-like peptide 1 (GLP-1) receptor agonist being studied as a once-weekly treatment for type 2 diabetes. In the trials, dulaglutide 1.5 mg was superior to placebo and to exenatide (AWARD-1),[1] metformin (AWARD-3)[2] and sitagliptin (AWARD-5) in reducing HbA1c (hemoglobin A1c) levels.[3],[4] In addition, a greater percentage of patients treated with dulaglutide 1.5 mg achieved an HbA1c goal of less than 7 percent versus all active comparators.

Findings from these three AWARD trials, which tested dulaglutide 1.5 mg and 0.75 mg against comparators, were presented today at the 73rd American Diabetes Association Scientific Sessions® in Chicago.

"Dulaglutide not only demonstrated superior glycemic control in these Phase III trials, it provided this control with once-weekly dosing, which may be attractive to both patients and healthcare professionals," said Guillermo Umpierrez, M.D., professor of medicine, division of endocrinology, metabolism, Emory University School of Medicine, and chief of diabetes and endocrinology, Grady Memorial Hospital. "It's encouraging news for this investigational GLP-1 receptor agonist."

In all three studies, patients taking dulaglutide 1.5 mg showed sustained weight loss for the duration of the trials. Patients taking dulaglutide 1.5 mg showed significant weight loss compared to patients taking sitagliptin (AWARD-5), and showed similar weight loss to patients taking comparators in AWARD-1 and AWARD-3.

Nausea was the most common adverse event reported across the studies for dulaglutide and was mostly mild to moderate and transient. No new safety signals were seen in any of the studies.

Dulaglutide showed low rates of hypoglycemia (blood glucose level less than or equal to 70 mg/dL) across these three AWARD trials. There were no cases of documented severe hypoglycemia in any of the trials.

"These results are a promising step forward in our effort to provide a new, once-weekly GLP-1 treatment option, giving patients another choice to help manage their diabetes," said Sherry Martin, M.D., senior medical director, Lilly Diabetes. "Dulaglutide represents an important component of our diabetes portfolio, as it could help us offer a broader range of options to patients across the diabetes spectrum."

Dulaglutide is among several diabetes molecules in Lilly's late-stage pipeline. The company has a number of potential new medicines in clinical development for the treatment of diabetes and its related conditions, encompassing both large and small molecules, and targeting a variety of mechanisms. Lilly expects to submit dulaglutide to regulatory authorities in 2013 and to submit detailed data from two additional AWARD studies for presentation at scientific meetings in 2014.

About the AWARD (Assessment of Weekly AdministRation of LY2189265 in Diabetes) Studies
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 1.5 mg, dosed once-weekly, is superior to placebo in reducing HbA1c from baseline at 26 weeks.

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, is non-inferior to metformin in reducing HbA1c from baseline at 26 weeks. Superiority testing was performed since the statistical criterion for non-inferiority was 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, is non-inferior to sitagliptin in reducing HbA1c from baseline at 52 weeks. Superiority testing was performed since the statistical criterion for non-inferiority was satisfied.

About Diabetes
Approximately 25.8 million Americans[5] and an estimated 371 million people[6] 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.[7]

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
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.

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[1]Wysham C, Blevins T, Arakaki R, et al. Efficacy and safety of dulaglutide vs placebo and exenatide in type 2 diabetes (AWARD-1). Abstract 66-OR. Presented at: American Diabetes Association (ADA) 73rd Scientific Sessions; June 21-25, 2013; Chicago, IL.

[2]Umpierrez GE, Manghi FP, Povedano ST, Shurzinske L, Pechtner V. Efficacy and safety of dulaglutide vs metformin in type 2 diabetes (AWARD-3). Abstract 69-OR. Presented at: American Diabetes Association (ADA) 73rd Scientific Sessions; June 21-25, 2013; Chicago, IL.

[3]Nauck MA, Weinstock RS, Umpierrez GE, et al. Efficacy and safety of dulaglutide vs sitagliptin after 52 weeks in type 2 diabetes (AWARD-5). Abstract 71-OR. Presented at: American Diabetes Association (ADA) 73rd Scientific Sessions; June 21-25, 2013; Chicago, IL.

[4]Weinstock RS, Umpierrez GE, Guerci B, Nauck MA, Boleyn KL, Skrivanek Z, Milicevic Z. Safety and efficacy of dulaglutide vs sitagliptin after 104 weeks in type 2 diabetes (AWARD-5). Abstract 1004-P. Presented at: American Diabetes Association (ADA) 73rd Scientific Sessions; June 21-25, 2013; Chicago, IL.

[5]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.

[6]International Diabetes Federation. Diabetes Atlas, 5th Edition: Fact Sheet. 2012.

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

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