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Lilly's Once-Weekly Dulaglutide Shows Non-Inferiority to Liraglutide in Head-to-Head Phase III Trial for Type 2 Diabetes

Once-Weekly Dulaglutide Hits Primary Endpoint in Sixth Consecutive AWARD Trial

INDIANAPOLIS, Feb. 25, 2014 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced positive top-line results of the sixth AWARD (Assessment of Weekly AdministRation of LY2189265 in Diabetes) trial for once-weekly dulaglutide, an investigational, long-acting glucagon-like peptide 1 (GLP-1) receptor agonist being studied as a treatment for type 2 diabetes.

In the AWARD-6 study, once-weekly dulaglutide 1.5 mg achieved the primary endpoint of non-inferiority to once-daily liraglutide 1.8 mg, as measured by the reduction of hemoglobin A1c (HbA1c) from baseline at 26 weeks.

"Dulaglutide is the only GLP-1 agonist to show non-inferiority against liraglutide's highest-approved dose in a Phase III trial," said Enrique Conterno, president of Lilly Diabetes. "The AWARD-6 data, along with the previous five AWARD studies, give us confidence that dulaglutide can be an important treatment option for people with type 2 diabetes. If approved, dulaglutide would be the only GLP-1 agonist that is both once-weekly and ready-to-use."

Adverse events were similar for patients in both treatment groups. The most frequently reported events were gastrointestinal-related. These findings are consistent with prior studies of once-weekly dulaglutide.

Once-weekly dulaglutide has been submitted to the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and other regulatory bodies. All previous five AWARD trials (1-5) included demonstrated superiority in reduction of HbA1c at the 1.5 mg dose against placebo and active comparators.

Lilly plans to present detailed data from the AWARD-6 (dulaglutide vs. liraglutide), AWARD-2 (dulaglutide vs. insulin glargine), and AWARD-4 (dulaglutide vs. insulin glargine; both in combination with insulin lispro) studies at scientific meetings later this year.

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 once-weekly 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, was superior to placebo in reducing HbA1c from baseline at 26 weeks.

AWARD-2 was a randomized, 78-week, open-label comparison of the effects of once-weekly dulaglutide and insulin glargine on glycemic control in patients with type 2 diabetes on metformin and glimepiride. 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 insulin glargine in reducing HbA1c from baseline at 52 weeks. Superiority testing was performed since the statistical criterion for non-inferiority was satisfied.

AWARD-3 was a randomized, 52-week, double-blind comparison of the effects of once-weekly 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 since the statistical criterion for non-inferiority was satisfied.

AWARD-4 was a randomized, 52-week, open-label comparison of the effects of once-weekly dulaglutide and insulin glargine, both in combination with insulin lispro, in patients with type 2 diabetes. The primary objective of the study, conducted in 884 patients, was to evaluate whether dulaglutide 1.5 mg, dosed once-weekly, in combination with insulin lispro, was non-inferior to insulin glargine in combination with insulin lispro, 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 once-weekly 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 since the statistical criterion for non-inferiority was satisfied.

AWARD-6 was a randomized, open-label, parallel-arm study comparing the effects of once-weekly dulaglutide and once-daily liraglutide on glycemic control in patients with type 2 diabetes on concomitant metformin. The primary objective of the study, conducted in 599 patients, was to evaluate whether dulaglutide 1.5 mg, dosed once-weekly, was non-inferior to liraglutide 1.8 mg, dosed once-daily, in reducing HbA1c from baseline at 26 weeks.

About Diabetes

Approximately 25.8 million Americans[1] and an estimated 382 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.[2]

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 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 approved by regulatory authorities 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, 6th Edition: Fact Sheet. 2013.

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