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Lilly Diabetes Presents Phase II Blood Pressure and Heart Rate Data on Investigational GLP-1 Analog Candidate, Dulaglutide, in Patients with Type 2 Diabetes at the 27th American Society of Hypertension Scientific Meeting

Phase II Trial Used Ambulatory Blood Pressure Monitoring to Evaluate Blood Pressure and Heart Rate for Dulaglutide

NEW YORK, May 22, 2012 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that dulaglutide, its investigational, long-acting glucagon-like peptide 1 (GLP-1) analog being studied as a once-weekly treatment for type 2 diabetes, met its primary endpoint of non-inferiority for mean 24-hour systolic blood pressure (SBP, or pressure while the heart contracts) after 16 weeks. The results came from a Phase II study that compared two doses of dulaglutide to placebo, using ambulatory blood pressure monitoring (ABPM) to characterize changes in blood pressure and heart rate. In addition, the 1.5 mg dulaglutide dose significantly reduced mean 24-hour SBP compared to placebo. These data were presented during a late-breaking clinical trial session at the 2012 Annual Scientific Meeting of the American Society of Hypertension (ASH) in New York.

"Cardiologists and hypertension specialists are increasingly involved with evaluating the cardiovascular effects of diabetes medications," said Keith C. Ferdinand, M.D., FACC, FAHA, FASH, professor of clinical medicine, Section of Cardiology, Tulane University School of Medicine. "This study used the gold standard measurement technique of ABPM to evaluate the blood pressure and heart rate effects of dulaglutide, an investigational GLP-1 receptor agonist."

ABPM is a non-invasive, fully automated technique to measure blood pressure at specific intervals (usually every 15-30 minutes) throughout an entire 24-hour period. This approach allows clinicians to more accurately characterize a person's blood pressure levels throughout a normal day.

"We are very encouraged by these clinical trial results, in addition to the rest of the clinical trial data we've seen to date for dulaglutide," said Gwen Krivi, Ph.D., vice president, product development, Lilly Diabetes. "Dulaglutide is currently in Phase III clinical trials, where it will continue to be evaluated on its efficacy to lower blood glucose levels, overall safety, weight effects and effects on cardiovascular outcomes. We believe dulaglutide, if approved, can bring significant benefits to people with type 2 diabetes."

Both dulaglutide doses were shown to be non-inferior (NI) (margin 3 mmHg) compared to placebo at week 16 for mean 24-hour SBP, which was the primary objective of the study. Since the NI criterion was satisfied, superiority testing was conducted, and the 1.5 mg dose demonstrated statistically significant reductions in mean 24-hour SBP compared to placebo.

- Dulaglutide 0.75 mg: -1.07 mmHg (97.3% CI: -2.83, 0.68)
- Dulaglutide 1.5 mg: -2.79 mmHg (97.3% CI: -4.58, -1.00)

Similar results were observed for comparisons at week 26.

The study also had several secondary objectives, including effects on mean 24-hour diastolic blood pressure (DBP, or pressure when the heart relaxes between beats) and mean 24-hour heart rate. For mean 24-hour DBP, the NI criterion (2.5 mmHg) was met for both dulaglutide doses compared to placebo at weeks 16 and 26.

For mean 24-hour heart rate, the 0.75 mg dulaglutide dose met the NI criterion (3 bpm) at both weeks 16 and 26 compared to placebo (1.62 bpm [97.3% CI: 0.32, 2.92] and 1.26 bpm [97.3% CI: -0.13, 2.64], respectively). The 1.5 mg dose did not meet the NI criterion at either week 16 (2.84 bpm [97.3% CI: 1.52, 4.16] or week 26 (3.50 bpm [97.3% CI: 2.10, 4.91]). This effect on heart rate is consistent with what has been observed for other compounds in the GLP-1 agonist class.

Both doses of dulaglutide demonstrated statistically significant reductions in HbA1c (average blood glucose levels over a three-month period) from baseline, compared to placebo, at weeks 16 and 26.

The most frequently reported adverse events were gastrointestinal (including diarrhea, nausea and vomiting). This is consistent with other GLP-1 agonists.

About the Study

This Phase II, randomized, double-blind, placebo-controlled, 26-week, parallel study included 755 patients with type 2 diabetes on one or more oral diabetes medications, of whom about 67 percent had a preexisting diagnosis of hypertension. Patients who were hypertensive took three or fewer antihypertensive medications, with a stable regimen for at least 30 days and no change on study. The study evaluated whether changes from baseline to week 16 in mean 24-hour SBP of dulaglutide 0.75 mg and dulaglutide 1.5 mg, dosed once-weekly, were NI to placebo, as measured by ABPM, using a NI margin of 3 mmHg. Superiority testing was performed if 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 we introduced the world's first commercial insulin. Today we work 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

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This press release contains forward-looking statements about dulaglutide that are based on Lilly's current 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, that dulaglutide 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, please see the company's latest Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. The company undertakes no duty to update forward-looking statements.

(Logo: <http://photos.prnewswire.com/prnh/20111111/DE03493LOGO>)

[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.

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