June 8, 2015

New Data Show Superiority of Lilly's Once-Weekly Trulicity™ (dulaglutide) to Lantus® (insulin glargine) in Patients with Type 2 Diabetes

Data presented at 75th American Diabetes Association Scientific Sessions® bolster existing information on Trulicity's safety and efficacy

INDIANAPOLIS, June 8, 2015 /PRNewswire/ -- Trulicity™ 1.5 mg and 0.75 mg provided superior hemoglobin A1c (A1C) reduction compared to Lantus® in a study of patients with type 2 diabetes and primarily enrolled from East Asia, according to new data presented by Eli Lilly and Company (NYSE: LLY). The head-to-head study was presented today at the 75th American Diabetes Association (ADA) Scientific Sessions in Boston.[1]

"Continuing to research our medicines beyond the initial clinical trial program is important for patients and for the ongoing study of diabetes," said Brad Woodward, M.D., senior medical director, Lilly Diabetes. "These results reinforce the value, safety and efficacy of once-weekly Trulicity for people in need of additional treatment when diet, exercise and oral medicines are not enough to give them the blood sugar control they need."

After 26 weeks, both doses of Trulicity were superior to Lantus in A1C reduction, and significantly more patients reached the recommended A1C target of less than 7 percent.

- A1C reductions from baseline: -1.7 percent (Trulicity 1.5 mg), -1.32 percent (Trulicity 0.75 mg), -1.15 percent (Lantus).
- Percentages of patients reaching target A1C levels (< 7 percent): 65 percent (Trulicity 1.5 mg), 54 percent (Trulicity 0.75 mg), 41 percent (Lantus).[1]

Patients treated with Trulicity 1.5 mg and 0.75 mg also lost an average of 1.51 kg and 0.88 kg respectively, while patients treated with Lantus gained 0.96 kg.[1]

Trulicity was well-tolerated in the study, showing fewer reports of hypoglycemia in patients treated with Trulicity 1.5 mg and 0.75 mg compared to Lantus. No severe hypoglycemia was reported. Other adverse events were gastrointestinal in nature, with more Trulicity-treated patients experiencing diarrhea (15.2 percent [Trulicity 1.5 mg], 8.4 percent [Trulicity 0.75 mg]) and nausea (8.7 percent [Trulicity 1.5 mg], 4.9 percent [Trulicity 0.75 mg]) compared to Lantus (1.6 percent [diarrhea] and 0.8 percent [nausea]). These results were consistent with previous Trulicity studies.[1]

Trulicity was approved by the U.S. Food and Drug Administration (FDA) in September 2014, and launched in the U.S. in November 2014. The European Commission granted marketing authorisation for Trulicity in November 2014, and launches are ongoing in the various countries. Additional regulatory applications are pending around the world.

About the study
This randomized, open-label, parallel-arm study compared the safety and efficacy of Trulicity 1.5 mg and 0.75 mg to Lantus. The primary objective of the study, conducted in 789 type 2 diabetes patients inadequately controlled on metformin and/or a sulfonylurea, was to evaluate whether Trulicity 1.5 mg was non-inferior to Lantus in reducing A1C from baseline at 26 weeks. The study enrolled participants primarily from China and also from Korea, Mexico and Russia. Participants had an average baseline A1C of 8.36 percent and continued to receive background treatment of metformin and/or a sulfonylurea.[1]

Indication and Limitations of Use for Trulicity
Trulicity is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

Trulicity is not recommended as first-line therapy for patients inadequately controlled on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans. Prescribe only if potential benefits outweigh potential risks. It has not been studied in patients with a history of pancreatitis and other antidiabetic therapies should be considered. Trulicity is not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. Trulicity is not a substitute for insulin and has not been studied in combination with basal insulin. Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is not for patients with pre-existing severe gastrointestinal disease.

Important Safety Information for Trulicity™

WARNING: RISK OF THYROID C-CELL TUMORS
In male and female rats, dulaglutide causes a dose-related and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure. It is unknown whether Trulicity causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of dulaglutide-induced rodent thyroid C-cell tumors has not been determined. Trulicity is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of Trulicity and inform them of symptoms of thyroid tumors (e.g., mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Trulicity.

Trulicity is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with a prior serious hypersensitivity reaction to dulaglutide or any of the product components.

Risk of Thyroid C-cell Tumors: Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist (GLP-1 RA), have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 RA use in humans. If serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging, the patient should be further evaluated.

Pancreatitis: Has been reported in clinical trials. Observe patients for signs and symptoms including persistent severe abdominal pain. If pancreatitis is suspected, discontinue Trulicity promptly. Do not restart if pancreatitis is confirmed. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Hypoglycemia: The risk of hypoglycemia is increased when Trulicity is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. Patients may require a lower dose of the sulfonylurea or insulin to reduce the risk of hypoglycemia.

Hypersensitivity Reactions: Systemic reactions were observed in patients receiving Trulicity in clinical trials. Instruct patients who experience symptoms to discontinue Trulicity and promptly seek medical advice.

Renal Impairment: In patients treated with GLP-1 RAs, there have been postmarketing reports of acute renal failure and worsening of chronic renal failure, sometimes requiring hemodialysis. A majority of reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. In patients with renal impairment, use caution when initiating or escalating doses of Trulicity and monitor renal function in patients experiencing severe adverse gastrointestinal reactions.

Severe Gastrointestinal Disease: Use of Trulicity may be associated with gastrointestinal adverse reactions, sometimes severe. Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Trulicity or any other antidiabetic drug.

The most common adverse reactions reported in ≥5% of Trulicity-treated patients in placebo-controlled trials (placebo, Trulicity 0.75 mg, and Trulicity 1.5 mg) were nausea (5.3%, 12.4%, 21.1%), diarrhea (6.7%, 8.9%, 12.6%), vomiting (2.3%, 6.0%, 12.7%), abdominal pain (4.9%, 6.5%, 9.4%), decreased appetite (1.6%, 4.9%, 8.6%), dyspepsia (2.3%, 4.1%, 5.8%), and fatigue (2.6%, 4.2%, 5.6%).

Gastric emptying is slowed by Trulicity, which may impact absorption of concomitantly administered oral medications. Use caution when oral medications are used with Trulicity. Drug levels of oral medications with a narrow therapeutic index should be adequately monitored when concomitantly administered with Trulicity. In clinical pharmacology studies, Trulicity did not affect the absorption of the tested, orally administered medications to a clinically relevant degree.

Pregnancy: There are no adequate and well-controlled studies of Trulicity in pregnant women. Use only if potential benefit outweighs potential risk to fetus.

Nursing Mothers: It is not known whether Trulicity is excreted in human milk. A decision should be made whether to discontinue nursing or to discontinue Trulicity, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness of Trulicity have not been established and use is not recommended in patients less than 18 years of age.

Please click to access Prescribing Information, including Boxed Warning about possible thyroid tumors including

thyroid cancer, and Medication Guide.

Please see Instructions for Use included with the pen.

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About Diabetes

Approximately 29 million Americans[2] and an estimated 387 million people 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

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 newsroom.lilly.com/social-channels.

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Trulicity™ is a trademark of Eli Lilly and Company.

Lantus® is a registered trademark of Sanofi.

This press release contains forward-looking statements about Trulicity for the treatment of type 2 diabetes along with diet and exercise. 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 Trulicity will 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.

[1] Gu L, Wang W, Nevarez Ruiz L, et. al. Efficacy and Safety of Once-Weekly Dulaglutide vs. Insulin Glargine in Combination with Metformin and/or a Sulfonylurea in Predominantly Asian Patients with Type 2 Diabetes. Abstract 280-OR. Presented at 75th American Diabetes Association (ADA) Scientific Sessions; June 5-9, 2015; Boston, MA.

[2] Centers for Disease Control and Prevention. *National Diabetes Statistics Report, 2014.* Available at: http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf. October 2014.

[3] International Diabetes Federation. *IDF Diabetes Atlas, 6th edn.* Brussels, Belgium: International Diabetes Federation, 2014. http://www.idf.org/diabetesatlas.

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SOURCE Eli Lilly and Company