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Lilly's Trulicity™ (dulaglutide) Now Available in U.S. Pharmacies

Once-weekly treatment for adults with type 2 diabetes comes in a pen with a no-see, no-handle needle

INDIANAPOLIS, Nov. 10, 2014 /PRNewswire/ -- The newest GLP-1 receptor agonist treatment option to help improve glycemic control type 2 diabetes in adults is now available in U.S. pharmacies. Eli Lilly and Company's (NYSE: LLY) Trulicity™ (dulaglutide) is a once-weekly glucagon-like peptide-1 receptor agonist (GLP-1 RA) designed with patients in mind. It comes in a single-dose pen and does not require the patient to mix, measure, or handle the needle.

To view the multimedia assets associated with this release, please click: http://www.multivu.com/players/English/7356751-eli-lilly-and-company-trulicity-dulaglutide-improve-glycemic-control-type-2-diabetes/

"Some adults with type 2 diabetes find that diet, exercise and oral medicines aren't enough to meet their treatment goals," said Dr. Laura Fernandez, senior medical advisor, Lilly Diabetes. "Trulicity may be an option for them as it has demonstrated proven glycemic control, only has to be taken once weekly, and comes in an easy-to-use pen."

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. It has not been studied in patients with a history of pancreatitis, and other antidiabetic therapies should be considered for patients with a history of pancreatitis. 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.

Trulicity has a Boxed Warning about potential risk of thyroid c-cell tumors including medullary thyroid carcinoma (MTC). It is contraindicated in patients with a personal history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) and in patients with a prior serious hypersensitivity reaction to dulaglutide or any of its product components.

The U.S. Food and Drug Administration approved Trulicity on Sept. 18, 2014 based on results from a number of studies of Trulicity used alone or in combination with commonly prescribed diabetes medications, including metformin, pioglitazone, glimepiride, and insulin lispro. (Study details are available below.) It is now available to patients in 0.75 mg and 1.5 mg doses, delivered in the single-dose Trulicity pen. In a separate usability study, most patients agreed the Trulicity pen was easy to use.

To help make the cost of therapy more manageable, the Trulicity Savings Card can reduce out-of-pocket costs to $25 for each prescription of Trulicity (up to a value of $150 per month) for a maximum of two years. This is available for commercially insured patients only. Savings cards and eligibility requirements can be found at www.Trulicity.com, in Trulicity sample packages, or in the patient education brochure.

About Diabetes
Approximately 29 million Americans[1] and an estimated 382 million people worldwide have type 1 and type 2 diabetes. [2] Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diabetes cases.[1] Diabetes is a chronic disease that occurs when the body either does not properly produce, or use, the hormone insulin.[2]

About Trulicity
Trulicity is a once-weekly, glucagon-like peptide-1 receptor agonist (GLP-1 RA) injectable prescription medicine indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Trulicity is not insulin. It acts like GLP-1, a natural hormone, helping the body release its own insulin when patients eat to control blood sugar.

Trulicity comes in a pen and does not require the patient to mix, measure, or handle the needle. It can be taken any time of day, with or without meals, and should be injected subcutaneously in the abdomen, thigh, or upper arm.

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. It has not been

studied in patients with a history of pancreatitis, and other antidiabetic therapies should be considered for patients with a history of pancreatitis. 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 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 could not be determined from clinical or nonclinical studies.

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). Routine serum calcitonin or thyroid ultrasound monitoring is of uncertain value in patients treated with Trulicity. Counsel regarding the risk factors and symptoms of thyroid tumors.

Trulicity is contraindicated in patients with a prior serious hypersensitivity reaction to dulaglutide or any of the product components.

Risk of Thyroid C-cell Tumors: Counsel patients regarding the risk of medullary thyroid carcinoma and the symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Patients with elevated serum calcitonin (if measured) and patients with thyroid nodules noted on physical examination or neck imaging should be referred to an endocrinologist for further evaluation.

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 therapy.

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 clinical trials in patients receiving Trulicity. 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 in placebo-controlled trials (placebo, Trulicity 0.75 mg and 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 Full Prescribing Information, including Boxed Warning about possible thyroid tumors including thyroid cancer, Medication Guide for Trulicity. Please click to access Instructions for Use that accompany the pen.

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About the AWARD Studies
AWARD-1 was a 52-week, randomized, placebo-controlled study evaluating the effects of Trulicity 1.5 mg (N=279; baseline A1C 8.1%) or 0.75 mg (N=280; baseline A1C 8.1%) and Byetta® (N=276; baseline A1C 8.1%) versus placebo (N=141; baseline A1C 8.1%) on glycemic control in adults with type 2 diabetes on maximally tolerated metformin and Actos. Patients were excluded based on previous use of a GLP-1 receptor agonist or chronic insulin therapy. The primary objective was to demonstrate superiority of once-weekly Trulicity 1.5 mg versus placebo at 26 weeks (change from baseline). At the 26-week primary endpoint, mean A1C reductions were Trulicity 1.5 mg: 1.5%; Trulicity 0.75 mg: 1.3%; Byetta: 1.0%; placebo: 0.5%.

AWARD-2 was a 78-week, randomized, open-label study evaluating the effects of Trulicity 1.5 mg (N=273; baseline A1C 8.2%) or 0.75 mg (N=272; baseline A1C 8.1%) and Lantus® (N=262; baseline A1C 8.1%) on glycemic control in adults with type 2 diabetes on maximally tolerated doses of metformin and glimepiride. Patients were excluded based on previous use of a GLP-1 receptor agonist or chronic insulin therapy. The primary objective was to demonstrate the noninferiority of once-weekly Trulicity 1.5 mg versus Lantus titrated to target on A1C at 52 weeks (change from baseline). At the 52-week primary endpoint, mean A1C reductions were Trulicity 1.5 mg: 1.1%; Trulicity 0.75 mg: 0.8%; Lantus: 0.6%.

AWARD-3 was a 52-week, randomized, double-blind study evaluating the effects of Trulicity 1.5 mg (N=269; baseline A1C 7.6%) or 0.75 mg (N=270; baseline A1C 7.6%) and metformin (N=268; baseline A1C 7.6%) on glycemic control in adults with early type 2 diabetes. Patients were excluded based on previous use of a GLP-1 receptor agonist or chronic insulin therapy. The primary objective of the study was to demonstrate the noninferiority of monotherapy with once-weekly Trulicity 1.5 mg versus metformin on A1C at 26 weeks (change from baseline). At the 26-week primary endpoint, mean A1C reductions were Trulicity 1.5 mg: 0.8%; Trulicity 0.75 mg: 0.7%; metformin: 0.6%.

AWARD-4 was a 52-week randomized, open-label comparator study (double-blind with respect to Trulicity dose assignment) evaluating the effects of Trulicity 1.5 mg (N=295; baseline A1C 8.5%) or 0.75 mg (N=293; baseline A1C 8.4%) and Lantus (N=296; baseline A1C 8.5%), both in combination with insulin lispro, with or without metformin, in adults with type 2 diabetes. Patients had to be treated for three months previously with stable doses of a conventional insulin regimen and were excluded based on previous use of a GLP-1 receptor agonist. The primary objective was to demonstrate the noninferiority of once-weekly Trulicity 1.5 mg versus Lantus titrated to target, both in combination with insulin lispro, with or without metformin, on A1C at 26 weeks (change from baseline). At the 26-week primary endpoint, mean A1C reductions were Trulicity 1.5 mg: 1.6%; Trulicity 0.75 mg: 1.6%; Lantus: 1.4%.

AWARD-5 was a 104-week, placebo-controlled, randomized, double-blind study comparing the effects of Trulicity 1.5 mg (N=279; baseline A1C 8.1%), 0.75 mg (N=281; baseline A1C 8.2%) and Januvia® (N=273; baseline A1C 8.0%) on glycemic control in adults with type 2 diabetes on metformin. Patients were excluded based on previous use of a GLP-1 receptor agonist or insulin therapy. The primary objective was to demonstrate the noninferiority of once-weekly Trulicity 1.5 mg versus Januvia on A1C at 52 weeks (change from baseline). At the 52-week primary endpoint, mean A1C reductions were Trulicity 1.5 mg: 1.1%; Trulicity 0.75 mg: 0.9%; Januvia: 0.4%.

About the Trulicity Pen Usability Study
People with type 2 diabetes, caregivers of people with diabetes, and healthcare professionals who treat diabetes participated in a study on the safe and effective use of the Trulicity pen and the instructions for the Trulicity pen. One hundred twenty-eight people completed a questionnaire on their experiences using the pen and the instructions. One question in the questionnaire asked for users' responses to, "overall easy to use the medication delivery device."

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, @LillyHealth on Twitter and http://newsroom.lilly.com/social-channels.

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Trulicity™ is a trademark of Eli Lilly and Company.
Januvia® is a registered trademark of Merck & Co., Inc.
Byetta® is a registered trademark of AstraZeneca.
Lantus® is a registered trademark of Sanofi-Aventis.

This press release contains forward-looking statements about dulaglutide that are based on Lilly's current expec-tations. 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 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 and Prevention. *National Diabetes Statistics Report, 2014.* Available at: http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf. October 2014.

[2] International Diabetes Federation. *IDF Diabetes Atlas, 6th edn.* Brussels, Belgium: International Diabetes Federation, 2013. http://www.idf.org/diabetesatlas.

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