Lilly's AWARD-11 trial studying higher investigational doses of Trulicity® (dulaglutide) demonstrated superiority in A1C reduction in people with type 2 diabetes

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INDIANAPOLIS, June 26, 2019 /PRNewswire/ -- Eli Lilly and Company's (NYSE: LLY) trial studying higher investigational doses of Trulicity® (dulaglutide) met its primary efficacy endpoint of superiority, significantly reducing A1C from baseline in people with type 2 diabetes, compared to once-weekly Trulicity 1.5 mg after 36 weeks. The trial also met the secondary efficacy endpoint for superiority on weight reduction. The safety and tolerability profile of the investigational dulaglutide doses was consistent with the known profile of Trulicity 1.5 mg.

AWARD-11, a phase 3 randomized, double-blind, parallel arm study, evaluated the safety and efficacy of dulaglutide 3.0 mg and 4.5 mg doses in 1,842 participants with type 2 diabetes.

"Diabetes is a progressive condition, which is why people may need to adjust their treatment to achieve further glycemic control," said Brad Woodward, M.D., global development leader, Incretins, Lilly. "Lilly chose to study additional doses of dulaglutide to provide more options for clinicians and people living with type 2 diabetes. We're encouraged by the superior results, which showed a significant reduction in A1C beyond the effective Trulicity doses already available."

The AWARD-11 trial will continue through 52 weeks to evaluate longer-term safety data and is expected to complete in late 2019. Lilly plans to submit to regulatory authorities by late 2019 and will share detailed results at a future date.

About the AWARD-11 Study
The phase 3, randomized, double-blind, parallel arm study included 1,842 participants with type 2 diabetes and evaluated the efficacy and safety of two investigational doses of dulaglutide (3.0 mg and 4.5 mg) compared to dulaglutide 1.5 mg. The primary objective of the study was to demonstrate that a once-weekly investigational dulaglutide dose (3.0 mg and/or 4.5 mg) was superior to the approved Trulicity 1.5 mg dose, as measured by A1C reduction from baseline, at 36 weeks in people with inadequately controlled type 2 diabetes on concomitant metformin therapy. The primary and secondary objectives could be met if one or both doses achieved statistical significance for A1C reduction. Secondary and exploratory outcomes include change in mean body weight, percentage of A1C reductions less than seven percent, fasting plasma glucose (FPG) and occurrence of hypoglycemic episodes through 36 and 52 weeks. All patients started the study at a dose of dulaglutide 0.75 mg and then increased the dose in a step-wise approach at four week intervals to their final randomized maintenance dose of 1.5 mg, 3.0 mg (via a 1.5 mg step), or 4.5 mg (via steps at 1.5 mg and 3.0 mg).

Indication and Limitations of Use for Trulicity®
Trulicity is a once-weekly injectable prescription medicine to improve blood sugar (glucose) in adults with type 2 diabetes mellitus. It should be used along with diet and exercise. Trulicity is not recommended as the first medication to treat diabetes. It has not been studied in people who have had inflammation of the pancreas (pancreatitis). Trulicity should not be used by people with type 1 diabetes, people with diabetic ketoacidosis, or people with a history of severe gastrointestinal (GI) disease. It is not a substitute for insulin. It has not been studied in children under 18 years of age.

Important Safety Information for Trulicity®

Patients should tell their healthcare provider if they get a lump or swelling in their neck, have hoarseness, trouble swallowing, or shortness of breath while taking Trulicity. These may be symptoms of thyroid cancer. In studies with rats or mice, Trulicity and medicines that work like Trulicity caused thyroid tumors, including thyroid cancer. It is not known if Trulicity will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people. Patients should not take Trulicity if they or any of their family members have ever had MTC or if they have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Patients should not take Trulicity if they have had an allergic reaction to dulaglutide or any of the other ingredients in Trulicity.

Trulicity should not be used in children under 18 years of age.

Trulicity may cause serious side effects, including:

- **Inflammation of the pancreas (pancreatitis).** If a patient has pain in their stomach area (abdomen) that is severe and will not go away, they should stop taking Trulicity and call their healthcare provider right away. The pain may happen with or without vomiting. It may be felt going from the abdomen through to the back.
- **Low blood sugar (hypoglycemia).** If patients are using another medicine that can cause low blood sugar (such as insulin or a sulfonylurea) while taking Trulicity, their risk for getting low blood sugar (hypoglycemia) may be higher. Signs and symptoms of low blood sugar may include dizziness, blurred vision, anxiety, irritability, mood changes, sweating, slurred speech, hunger, confusion or drowsiness, shakiness, weakness, headache, fast heartbeat, or feeling jittery. Patients should talk to their healthcare provider about low blood sugar and how to manage it.

- **Serious allergic reactions**. Patients should stop taking Trulicity and get medical help right away if they have symptoms of a serious allergic reaction including: swelling of the face, lips, tongue or throat; problems breathing or swallowing; severe rash or itching; fainting or feeling dizzy; or very rapid heartbeat.
- **Acute kidney injury.** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration). This may cause kidney problems to get worse.
- **Severe stomach problems.** Trulicity may cause stomach problems, which could be severe.

Patients should tell their healthcare provider if they:

- *have or have had problems with their pancreas, kidneys, or liver.*
- *have severe problems with their stomach, such as slowed emptying of the stomach (gastroparesis) or problems with digesting food.*
- *have any other medical conditions.*
- *are pregnant or plan to become pregnant, or if they become pregnant while taking Trulicity. It is not known if Trulicity will harm their unborn baby.*
- *are breastfeeding or plan to breastfeed. It is not known if Trulicity passes into breast milk. Patients should not use Trulicity while breastfeeding without first talking to their healthcare provider.*
- *are taking other medicines including prescription and over-the-counter medicines, vitamins, and herbal supplements. Trulicity may affect the way some medicines work and some medicines may affect the way Trulicity works.*
- *are taking other medicines to treat diabetes, including insulin or sulfonylureas.*

If patients take too much Trulicity, they should call their healthcare provider or go to the nearest emergency room right away.

The most common side effects with Trulicity may include: *nausea, diarrhea, vomiting, abdominal pain and decreased appetite. Patients should talk to their healthcare provider about any side effect that bothers them or does not go away. These are not all the possible side effects of Trulicity. Patients should call their doctor for medical advice about side effects.*

Patients are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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 30 million Americans[1] and an estimated 425 million adults worldwide have diabetes.[2] Type 2 diabetes is the most common type internationally, accounting for an estimated 90 to 95 percent of all diabetes cases in the United States alone.[1] Diabetes is a chronic disease that occurs when the body 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, collaboration and quality manufacturing we strive to make life better for people affected by diabetes. We offer a wide range of therapies and a continued determination to provide real solutions—from medicines and technologies to support programs and more. For the latest updates, visithttp://www.lillydiabetes.com/ or follow us on Twitter: @LillyDiabetes and Facebook: LillyDiabetesUS.

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 www.lilly.com/newsroom/social-channels. P-LLY

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This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about dulaglutide 3.0 and/or 4.5 mg as a potential treatment for patients with diabetes and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results will be consistent with the results to date or that dulaglutide 3.0 and/or 4.5 mg will receive regulatory approvals. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

1. Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2017.
2. International Diabetes Federation. *IDF Diabetes Atlas*, 8th edn. Brussels, Belgium: International Diabetes Federation, 2017. http://www.diabetesatlas.org.

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