Investigational Doses of Lilly's Once-Weekly Trulicity® (dulaglutide) Show Promise in Delivering Powerful Efficacy in People with Type 2 Diabetes

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Data from a Phase 2 trial will be presented for the first time at the ADA's 78th Scientific Sessions®

INDIANAPOLIS, June 23, 2018 /PRNewswire/ -- Two investigational doses of Lilly's dulaglutide (4.5 mg and 3.0 mg), as well as Trulicity® (dulaglutide) 1.5 mg, provided significantly better blood sugar control with weight benefits compared to placebo in adults with type 2 diabetes.[1] Data from this Phase 2 study will be presented for the first time today in an oral session at the American Diabetes Association's (ADA) 78th Scientific Sessions® in Orlando. Trulicity is Eli Lilly and Company's (NYSE: LLY) once-weekly, injectable glucagon-like peptide-1 (GLP-1) receptor agonist (RA) approved to improve blood sugar (glucose) in adults with type 2 diabetes. Trulicity should be used along with diet and exercise.

"The progressive nature of type 2 diabetes often means that people must continue advancing treatment throughout the natural development of their condition," said Juan P. Frias, M.D., President and Principal Investigator, National Research Institute. "Trulicity is an effective, once-weekly GLP-1 RA option, and this study of investigational doses shows potential in providing further improved blood glucose control without changing treatment."

At the study's primary endpoint of 18 weeks, the investigational dulaglutide 4.5 mg and 3.0 mg doses, as well as the currently approved Trulicity 1.5 mg dose, led to superior A1C reductions from baseline in people with type 2 diabetes who remained on treatment throughout the study* (-1.50 percent (4.5 mg), -1.47 percent (3.0 mg), -1.24 percent (1.5 mg)) compared to placebo (-0.42 percent). The investigational dulaglutide doses also led to significant weight loss (-4.4 kg (4.5 mg), -4.2 kg (3.0 mg)) compared to placebo (-1.6 kg), as did Trulicity 1.5 mg (-2.9 kg).[1]

The most commonly reported side effects were gastrointestinal-related and consistent with the GLP-1 RA class. These events included nausea (30.3 percent (4.5 mg), 24.1 percent (3.0 mg), 22.2 percent (1.5 mg)) and vomiting (13.2 percent (4.5 mg), 10.1 percent (3.0 mg), 11.1 percent (1.5 mg)). Trulicity 1.5 mg had a similar side effect profile to previous studies. No participants in any of the treatment groups experienced severe hypoglycemia.[1]

"Once-weekly Trulicity offers people with type 2 diabetes a significant opportunity to reach their blood sugar goals and achieve low hypoglycemia rates with the potential for weight loss," said Brad Woodward, M.D., senior medical director, Lilly Diabetes. "We're always looking for opportunities to provide meaningful choices for people with diabetes, which is why we're studying investigational dulaglutide doses beyond the two effective Trulicity doses already approved."

The safety and efficacy of the dulaglutide investigational doses are being studied further in a large, Phase 3 clinical trial, AWARD-11. The study is expected to complete in 2019.

About the Phase 2 Study
The double-blind, randomized, parallel arm, placebo-controlled, 18-week Phase 2 study evaluated the efficacy and safety of two investigational doses of dulaglutide – 4.5 mg and 3.0 mg – compared to placebo, in people with type 2 diabetes with or without metformin. The primary objective of the study, in 318 patients in six countries, was to demonstrate the superiority of the investigational dulaglutide doses and the approved Trulicity 1.5 mg dose, to placebo on A1C reduction from baseline.

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®
Tell your healthcare provider if you get a lump or swelling in your 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. Do not take Trulicity if you or any of your family members have ever had MTC or if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Do not take Trulicity if you 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 your pancreas (pancreatitis).** If you have pain in your stomach area (abdomen) that is severe and will not go away, stop taking Trulicity and call your healthcare provider right away. The pain may happen with or without vomiting. It may be felt going from your abdomen through to your back.

- **Low blood sugar (hypoglycemia).** If you are using another medicine that can cause low blood sugar (such as insulin or a sulfonylurea) while taking Trulicity, your 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. Talk to your healthcare provider about low blood sugar and how to manage it.
- **Serious allergic reactions.** Stop taking Trulicity and get medical help right away if you have symptoms of a serious allergic reaction including: swelling of your face, lips, tongue or throat; problems breathing or swallowing; severe rash or itching; fainting or feeling dizzy; or very rapid heartbeat.
- **Kidney problems (kidney failure).** 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.

Tell your healthcare provider if you:

- have or have had problems with your pancreas, kidneys, or liver.
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- have any other medical conditions.
- are pregnant or plan to become pregnant, or if you become pregnant while taking Trulicity. It is not known if Trulicity will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Trulicity passes into your breast milk. You should not use Trulicity while breastfeeding without first talking to your 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 you take too much Trulicity, call your 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. Talk to your healthcare provider about any side effect that bothers you or does not go away. These are not all the possible side effects of Trulicity. Call your doctor for medical advice about side effects.

You 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[2] and an estimated 425 million adults worldwide have diabetes.[3] 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.[2] Diabetes is a chronic disease that occurs when the body does not properly produce or use the hormone insulin.

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.

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*Treatment effect of dulaglutide versus placebo for all randomized subjects while on treatment without use of rescue medication was assessed by Mixed Models for Repeated Measurements (MMRM).

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about dulaglutide investigational doses as a treatment for type 2 diabetes and Lilly's current beliefs. 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 study findings to date, that Trulicity will receive additional regulatory approvals or that Trulicity will prove to be commercially successful. 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.

References:

1. Frias, Juan P., et al. Efficacy and Safety of an Expanded Dulaglutide Dose Range—A Phase 2, Placebo-Controlled Trial in T2D Patients on Metformin. Abstract 126-OR. Presented at 78th American Diabetes Association Scientific Sessions; June 22-26, Orlando, FL.
2. Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Available at: https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf. November 2017.
3. International Diabetes Federation. IDF Diabetes Atlas, 8th edn, 2017. Available at: http://www.diabetesatlas.org/. November 2017.

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