New Data Show Lilly's Trulicity® (dulaglutide) in Combination with an SGLT-2 Inhibitor Improves Blood Sugar Control in People with Type 2 Diabetes

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INDIANAPOLIS, Feb. 26, 2018 /PRNewswire/ -- Trulicity® (dulaglutide) significantly improves A1C (average blood sugar concentration over two to three months) when added to ongoing treatment with a sodium-glucose co-transporter-2 (SGLT-2) inhibitor, according to results from AWARD-10, a new Phase 3b clinical study.[1] These data were published online first in *The Lancet Diabetes & Endocrinology*. Trulicity is Eli Lilly and Company's (NYSE: LLY) once-weekly, injectable glucagon-like peptide-1 (GLP-1) receptor agonist approved to improve blood sugar (glucose) in adults with type 2 diabetes. Trulicity should be used along with diet and exercise.

"I've seen in my practice that even with effective oral medicines like SGLT-2 inhibitors and metformin, many adults with type 2 diabetes may still need additional therapy to maintain their blood sugar levels," said Bernhard Ludvik, M.D., associate professor of medicine, Rudolfstiftung Hospital Vienna and AWARD-10 lead author. "The AWARD-10 results suggest that the combination of once-weekly Trulicity and an SGLT-2 inhibitor shows significant promise in helping more people with type 2 diabetes reach their treatment goals."

At the study's primary endpoint of 24 weeks, both Trulicity 1.5 mg and 0.75 mg added to ongoing treatment with an SGLT-2 inhibitor demonstrated statistically superior glycemic control (-1.34 percent, -1.21 percent for Trulicity 1.5 mg and 0.75 mg, respectively) compared to an SGLT-2 inhibitor with placebo (-0.54 percent). Further, significantly more people in the Trulicity groups reached target A1C levels of less than 7 percent and less than or equal to 6.5 percent:[1]

- Trulicity 1.5 mg: 71 percent (<7 percent); 50 percent (≤6.5 percent)
- Trulicity 0.75 mg: 60 percent (<7 percent); 38 percent (≤6.5 percent)
- Placebo: 32 percent (<7 percent); 14 percent (≤6.5 percent)

Additional results showed that Trulicity 1.5 mg combined with an SGLT-2 inhibitor was associated with greater average weight loss (-3.1 kg) compared to placebo (-2.1 kg). An average weight reduction of -2.6 kg was seen in the Trulicity 0.75 mg group.

The most commonly reported adverse events associated with Trulicity were gastrointestinal-related and consistent with previous studies. Nausea (15 percent, 5 percent, 4 percent), vomiting (4 percent, 3 percent, 1 percent) and diarrhea (6 percent, 10 percent, 3 percent) were more frequent in the Trulicity 1.5 mg and 0.75 mg groups compared to placebo. One severe hypoglycemic event was documented in the Trulicity 0.75 mg group. No new Trulicity-related safety concerns were identified.[1]

"Managing type 2 diabetes with diet, exercise and oral medications may require the addition of injectable therapy for some people, given the progressive nature of the disease," said Brad Woodward, M.D., senior medical director, Lilly Diabetes. "AWARD-10 showed that Trulicity, when used in combination with an SGLT-2 inhibitor and metformin, may be effective and well tolerated in people with type 2 diabetes."

About the AWARD-10 Study
The Phase 3b, double-blind, parallel-arm, placebo-controlled, 24-week AWARD-10 study compared the safety and efficacy of Trulicity 1.5 mg and 0.75 mg in combination with sodium glucose co-transporter-2 (SGLT-2) inhibitors to placebo plus SGLT-2 inhibitors in people with type 2 diabetes inadequately controlled with SGLT-2 inhibitors, with or without metformin. The primary objective of this study, in 424 patients in eight countries with a mean baseline A1C of 8.04 percent, was to demonstrate superiority of Trulicity plus an SGLT-2 inhibitor to placebo plus an SGLT-2 inhibitor on A1C reduction.

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, visit http://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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This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Trulicity added to SGLT-2 inhibitor treatment as a treatment of type 2 diabetes, along with diet and exercise, 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.

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