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## **New Data Show Lilly's Once-Weekly Trulicity® (dulaglutide) in Combination with Insulin Glargine Improves Glycemic Control in People with Type 2 Diabetes**

INDIANAPOLIS, June 12, 2016 /PRNewswire/ -- New data from a completed Phase 3 trial show Trulicity® (dulaglutide) 1.5 mg significantly reduced hemoglobin A1c (A1C) and body weight as an add-on to insulin glargine without increasing the risk of low blood sugar after 28 weeks compared to placebo plus insulin glargine. Trulicity is Eli Lilly and Company's (NYSE: LLY) once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist that is used along with diet and exercise for the treatment of type 2 diabetes. Data from the Trulicity AWARD-9 trial were presented today at the 76<sup>th</sup> American Diabetes Association Scientific Sessions (ADA) in New Orleans, Louisiana.

"Some people with type 2 diabetes require the use of more than one therapy to reach their glucose management goals and as a result, there is a concern about the risk of causing low sugar levels," said Paolo Pozzilli, M.D., professor of endocrinology and metabolic diseases at University Campus Bio-Medico in Rome, Italy and lead author. "AWARD-9 demonstrates that Trulicity may help people with diabetes who continue to experience inadequate glycemic control on insulin glargine alone reach their treatment goals."

Lilly's AWARD program has consistently shown Trulicity's efficacy in improving glycemic control. Data from AWARD-9 builds on the available data, demonstrating Trulicity's viability for use in combination with insulin glargine to help people with type 2 diabetes reach treatment goals.

After 28 weeks of treatment, Trulicity 1.5 mg plus insulin glargine significantly reduced A1C from baseline (1.44 percent) compared to placebo with insulin glargine (0.67 percent). Also:

- ▮ Significantly more people treated with Trulicity 1.5 mg plus insulin glargine achieved an A1C of less than 7 percent (69.3 percent) compared to placebo with insulin glargine (35.1 percent);
- ▮ The group treated with Trulicity 1.5 mg plus insulin glargine saw significant reductions in fasting serum glucose levels (the amount of sugar in the blood in a fasting state) with a 44.63 mg/dL reduction compared to the group treated with placebo plus insulin glargine (27.90 mg/dL reduction); and
- ▮ Study participants treated with Trulicity 1.5 mg experienced significant weight loss (-1.91 kg) compared to participants treated with placebo plus insulin glargine, who gained weight (0.50 kg).
- ▮ During the course of the study, insulin glargine was titrated using a treat-to-target algorithm in both groups; after 28 weeks, participants treated with Trulicity 1.5 mg took an average of 13.19 units less of insulin glargine than those treated with placebo plus insulin glargine (51.42 vs. 64.61 U).

The most commonly reported adverse events for people taking Trulicity in AWARD-9 were gastrointestinal-related and consistent with prior Trulicity studies, including nausea (12 percent) and diarrhea (11.3 percent). Hypoglycemia rates were similar in the Trulicity 1.5 mg plus insulin glargine group (7.69 events/patient/year) compared to those treated with placebo plus insulin glargine (8.56 events/patient/year). One severe hypoglycemic event was documented in the Trulicity 1.5 mg plus insulin glargine group.

"Despite best efforts to manage their A1C with diet and oral agents, many people with type 2 diabetes transition to injectable therapy as a natural part of the disease progression," said Zvonko Milicevic, senior medical fellow, Lilly Diabetes. "For people with type 2 diabetes who are inadequately controlled on insulin glargine alone, AWARD-9 may show that Trulicity is a treatment option that could significantly reduce A1C when used in combination with their current insulin therapy."

### **About the AWARD-9 Study**

This Phase 3, randomized, double-blind, placebo-controlled, 28-week study evaluated the efficacy and safety of once-weekly Trulicity (dulaglutide) 1.5 mg as an add-on to insulin glargine compared to placebo with insulin glargine. The primary objective of this study, in 300 patients in five countries with a mean baseline A1C of 8.4 percent, was to demonstrate superiority of Trulicity 1.5 mg to placebo on A1C reduction in type 2 diabetes patients inadequately treated with insulin glargine, with or without metformin.

### **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. 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 a history of severe gastrointestinal (GI) disease, people with type 1 diabetes, or people with diabetic ketoacidosis. It is not a substitute for insulin. It has not been studied with long-acting insulin or 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 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, such as itching, rash, or difficulty breathing.
- | **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.

### **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.

**The most common side effects with Trulicity may include:** nausea, diarrhea, vomiting, decreased appetite, and indigestion. 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](http://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.

## About Diabetes

Approximately 29 million Americans<sup>1</sup> and an estimated 415 million people worldwide have type 1 and type 2 diabetes.<sup>2</sup> 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 does not either properly produce or use the hormone insulin.<sup>1</sup>

## 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](http://www.lillydiabetes.com) or follow us on Twitter: @LillyDiabetes.

## 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](http://www.lilly.com) and [newsroom.lilly.com/social-channels](http://newsroom.lilly.com/social-channels).

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Trulicity<sup>®</sup> is a registered trademark owned or licensed by Eli Lilly and Company, its subsidiaries, or affiliates.

*This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Trulicity 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.*

## References

<sup>1</sup> 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.

<sup>2</sup> International Diabetes Federation. *IDF Diabetes Atlas*, 7th edn. Brussels, Belgium: International Diabetes Federation, 2015. <http://www.idf.org/diabetesatlas>.

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