December 1, 2015

# New Data Show Lilly's Once-Weekly Trulicity® (dulaglutide) is Effective as Add-on Treatment to Sulfonylurea

## Trulicity 1.5 mg Demonstrates Superior Efficacy in AWARD-8 Trial

INDIANAPOLIS, Dec. 1, 2015 /PRNewswire/ -- New data from a completed Phase 3 trial show Trulicity® (dulaglutide) 1.5 mg plus a sulfonylurea was significantly more effective than a sulfonylurea alone in lowering hemoglobin A1c (A1C) from baseline after 24 weeks of treatment.[1] Trulicity is Eli Lilly and Company's (NYSE: LLY) once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist for the treatment of type 2 diabetes. These data, from the Trulicity AWARD-8 clinical trial, were presented for the first time today at the 2015 International Diabetes Federation (IDF) World Diabetes Congress in Vancouver, Canada.

"For patients who cannot tolerate or have contraindications to metformin, a sulfonylurea is often prescribed as first-line therapy for type 2 diabetes," said Kathleen Dungan, M.D., endocrinologist, associate professor, The Ohio State University Wexner Medical Center, and lead study author. "This study affirms that Trulicity is efficacious and well-tolerated as an add-on to sulfonylurea therapy, which can help prescribers make treatment decisions for their individual patients."

At the primary endpoint of 24 weeks, Trulicity 1.5 mg plus sulfonylurea provided superior A1C reduction from baseline (-1.38 percent) compared to sulfonylurea with placebo (-0.11 percent). Additionally:

- Significantly more patients treated with Trulicity 1.5 mg plus sulfonylurea achieved an A1C of less than 7 percent (55.3 percent) compared to sulfonylurea with placebo (18.9 percent); and
- Trulicity plus a sulfonylurea significantly reduced fasting serum glucose levels (the amount of sugar in the blood in a fasting state) compared to sulfonylurea with placebo (-30.60 mg/dL vs. +2.93 mg/dL).

As a secondary endpoint of the study, Trulicity plus a sulfonylurea showed weight reduction from baseline (-0.91 kg), though the difference compared to sulfonylurea with placebo did not reach statistical significance.[1]

The most commonly reported adverse events were gastrointestinal-related and consistent with prior Trulicity studies, including nausea (10.5 percent) and diarrhea (8.4 percent). There were no cases of pancreatitis or pancreatic cancer in either treatment group. As expected, more patients treated with Trulicity plus a sulfonylurea experienced episodes of hypoglycemia compared to those treated with sulfonylurea alone, though the overall incidence of documented symptomatic hypoglycemia was low in the Trulicity group (11.3 percent) and there were no reported cases of severe hypoglycemia in either group.[1]

"The AWARD-8 study demonstrated Trulicity's safety and efficacy as add-on therapy to sulfonylurea," said Jessie Fahrbach, M.D., medical director, Lilly Diabetes. "These data add to the comprehensive body of evidence for Trulicity, reinforcing its value as a type 2 diabetes treatment option."

### About the AWARD-8 Study[1]

This Phase 3, randomized, double-blind, placebo-controlled, 24-week study compared the efficacy and safety of once-weekly Trulicity 1.5 mg to placebo in sulfonylurea-treated patients with type 2 diabetes and inadequate glycemic control. The primary objective of the study, in 299 patients with a mean baseline A1C of 8.4 percent, was to demonstrate superiority of Trulicity 1.5 mg to placebo on A1C reduction in patients treated with sulfonylurea monotherapy.

### Indication and Limitations of Use for Trulicity

Trulicity is a once-weekly injectable prescription medicine to improve blood sugar 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. Trulicity should not be used by people with a history of severe gastrointestinal 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 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 29 million Americans[2] and an estimated 415 million people worldwide have type 1 and type 2 diabetes.[3] 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.[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 work to meet the diverse needs of people with diabetes through research and collaboration, a broad and growing product portfolio and a continued commitment to providing real solutions—from medicines to support programs and more—to make lives

better. 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 and newsroom.lilly.com/social-channels.

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*This press release contains forward-looking statements about Trulicity for the treatment of type 2 diabetes along with diet and exercise. It reflects Lilly's current beliefs; however, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that Trulicity will prove to be commercially successful. For further discussion of these and other risks and uncertainties, please see Lilly's latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.*

**References**


[1] Dungan, K, Weitgasser R, Manghi FP, *et. al.* Efficacy and Safety of Once Weekly Dulaglutide Added on to Sulfonylurea in Type 2 Diabetes (AWARD-8). Abstract 0219-PD. Presented at 2015 International Diabetes Federation (IDF) World Congress; 30 November - 4 December, Vancouver, Canada.

[2] 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.

[3] International Diabetes Federation. *IDF Diabetes Atlas,* 7th edn. Brussels, Belgium: International Diabetes Federation, 2015. http://www.idf.org/diabetesatlas.



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