



First patient dose delivered for Lilly's tirzepatide cardiovascular outcomes trial

June 9, 2020

INDIANAPOLIS, June 9, 2020 /PRNewswire/ -- The first patient dose has been delivered in SURPASS-CVOT, the phase 3 cardiovascular outcomes trial for tirzepatide, Eli Lilly and Company's (NYSE: LLY) investigational dual GIP and GLP-1 receptor agonist. The study will assess both non-inferiority and superiority of tirzepatide in a head-to-head trial against Trulicity® (dulaglutide) 1.5 mg – the market leading GLP-1 receptor agonist.

"Lilly is making a bold move by comparing tirzepatide to Trulicity, which is already proven to significantly reduce the risk of major adverse cardiovascular events," said study co-chairs David A. D'Alessio, M.D., Chief in the Division of Endocrinology and Metabolism, Duke University School of Medicine, and Stephen Nicholls, M.B.,B.S., Ph.D., Director of the Monash University Victorian Heart Institute, on behalf of the study's Academic Executive Committee. "SURPASS-CVOT will provide clinicians of people with type 2 diabetes and established cardiovascular disease with important evidence about the potential of tirzepatide to deliver outcomes beyond today's best-in-class medicines."

SURPASS-CVOT ([NCT04255433](#)) includes 12,500 participants with type 2 diabetes and atherosclerotic cardiovascular disease from 30 countries. The primary endpoint measures time to first occurrence of MACE-3, the composite endpoint of CV death, myocardial infarction or stroke. Key secondary endpoints measure time to all-cause mortality and time to occurrence of each component of the primary endpoint. Lilly anticipates the trial will take just over four years to complete.

"We are constantly evaluating the needs of people living with diabetes and are committed to researching innovative medicines that reflect the evolution in the standards of diabetes care," said Jeff Riesmeyer, Distinguished Medical Fellow, Lilly. "We are confident in the potential of tirzepatide to help people with type 2 diabetes achieve additional benefits beyond blood glucose control alone and look forward to results from SURPASS-CVOT."

PURPOSE AND SAFETY SUMMARY WITH WARNINGS

Important Facts About Trulicity® (Trū-li-si-tee). It is also known as dulaglutide.

TRULICITY is an injectable prescription medicine for adults with type 2 diabetes used to improve blood sugar (glucose) and used to reduce the risk of major cardiovascular events such as death, heart attack, or stroke in people who have heart disease or multiple cardiovascular risk factors.

- You take it once a week by injecting it under the skin of your stomach, thigh, or upper arm. Use Trulicity together with the diet and exercise that your doctor recommends. Trulicity is not insulin.

Warnings

Trulicity may cause tumors in the thyroid, including thyroid cancer. Watch for possible symptoms, such as a lump or swelling in the neck, trouble swallowing, hoarseness, or shortness of breath. If you have a symptom, tell your doctor.

- Do not use Trulicity if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC).
- Do not use Trulicity if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Do not use Trulicity if you are allergic to dulaglutide or other ingredients in Trulicity.

Ask your doctor how to recognize the serious side effects below and what to do if you think you have one:

Inflamed pancreas (pancreatitis). Stop using Trulicity and call your healthcare provider right away if you have severe pain in your stomach area (abdomen), with or without vomiting, that will not go away. You may feel the pain from your abdomen to your back.

Changes in vision. Tell your healthcare provider if you have changes in vision during treatment with Trulicity.

Low blood sugar (hypoglycemia). Signs and symptoms of low blood sugar may include dizziness or light-headedness, confusion or drowsiness, headache, blurred vision, slurred speech, fast heartbeat, sweating, hunger, shakiness, feeling jittery, weakness, anxiety, irritability or mood changes.

Serious allergic reactions. Stop using Trulicity and get medical help right away if you have any symptoms of a serious allergic reaction which may include: swelling of your 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.

Common side effects

The most common side effects of Trulicity include nausea, diarrhea, vomiting, abdominal pain and decreased appetite.

These are not all the possible side effects of Trulicity.

Tell your doctor if you have any side effects. **You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Before using

- **Your healthcare provider should show you how to use Trulicity before you use it for the first time.**
- **Before you use Trulicity, talk to your doctor about low blood sugar and how to manage it.**

Review these questions with your doctor:

- Do you have other medical conditions, including problems with your pancreas, kidneys, liver, or stomach, or have a history of diabetic retinopathy?
- Do you take other diabetes medicines, such as insulin or sulfonylureas?
- Do you take any other prescription medicines or over-the-counter drugs, vitamins or herbs?

Review the list below with your doctor. Trulicity may not be right for you if:

- You are pregnant or plan to become pregnant or breastfeeding or plan to breastfeed.
- You have type 1 diabetes or diabetic ketoacidosis.
- You have or have had an inflamed pancreas (pancreatitis).
- You have severe intestinal or stomach problems, such as slowed emptying or problems with digesting food.
- You are a child under 18 years old.

How to take

- Read the Instructions for Use that come with Trulicity.
- Use Trulicity exactly as your doctor says.
- Do not share your Trulicity pen, syringe or needles with another person.
- Do not give Trulicity to other people.
- If you take too much Trulicity, call your healthcare provider or seek medical advice promptly.

Learn more

For more information, call 1-844-TRU-INFO (1-844-878-4636) or go to www.TRULICITY.com.

This summary provides basic information about Trulicity but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other healthcare provider about Trulicity and how to take it. Your doctor is the best person to help you decide if Trulicity is right for you.

Please see full [Prescribing Information](#), including Boxed Warning about possible thyroid tumors including thyroid cancer, and [Medication Guide](#).

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About Diabetes

An estimated 463 million adults worldwide¹ have diabetes. Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diabetes cases². 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 and related conditions. We work to deliver breakthrough outcomes through innovative 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](https://twitter.com/LillyDiabetes) and Facebook: [LillyDiabetesUS](https://www.facebook.com/LillyDiabetesUS).

About Eli Lilly and Company

Lilly is a global health care leader that unites caring with discovery to create medicines that 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 lilly.com and lilly.com/newsroom. P-LLY

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about tirzepatide as a potential treatment for patients with type 2 diabetes and atherosclerotic cardiovascular disease and Trulicity (dulaglutide) as a treatment for patients with type 2 diabetes and used to reduce the risk of major cardiovascular events, 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, that tirzepatide will achieve its primary study endpoints or receive regulatory approvals, or that Trulicity will continue 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.

¹ International Diabetes Federation. IDF Diabetes Atlas, 9th edn. Brussels, Belgium: International Diabetes Federation, 2019. Available at: <http://diabetesatlas.org>.

² Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept. of Health and Human Services; 2020.

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The Lilly logo is rendered in a vibrant red, cursive script font. The letters are fluid and interconnected, with a prominent 'L' at the beginning and a long, sweeping tail on the 'y'.

 View original content to download multimedia: <http://www.prnewswire.com/news-releases/first-patient-dose-delivered-for-lillys-tirzepatide-cardiovascular-outcomes-trial-301072348.html>

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