



Trulicity® (dulaglutide) is the first and only type 2 diabetes medicine approved to reduce cardiovascular events in adults with and without established cardiovascular disease

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New indication reflects distinct patient population in the REWIND study, including primarily people with multiple cardiovascular risk factors but without established cardiovascular disease

INDIANAPOLIS, Feb. 21, 2020 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) has approved Trulicity® (dulaglutide) for the reduction of major adverse cardiovascular events (MACE) in adults with type 2 diabetes who have established cardiovascular (CV) disease or multiple cardiovascular risk factors. This decision makes Eli Lilly and Company's (NYSE: LLY) Trulicity the first and only type 2 diabetes medicine approved to reduce the risk of MACE for both primary and secondary prevention populations.*

The new indication reflects the differentiated patient population of REWIND, the Trulicity cardiovascular outcomes trial. While all participants had CV risk factors, the study consisted primarily of people without established CV disease. REWIND showed a significant risk reduction in MACE, a composite endpoint of nonfatal myocardial infarction (heart attack), nonfatal stroke or CV death. Results demonstrated consistent MACE risk reduction with Trulicity across major demographic and disease subgroups. Trulicity's safety profile was consistent with the GLP-1 receptor agonist (RA) class. The most common adverse events leading to the discontinuation of Trulicity were gastrointestinal events.

"The trial was designed to study a broad population of people living with type 2 diabetes, reflective of those in the general population. We therefore assessed the effect of Trulicity in people with established cardiovascular disease as well as those with multiple cardiovascular risk factors," said Hertzell Gerstein, M.D., MSc, FRCPC, professor of medicine and deputy director of the Population Health Institute at McMaster University and Hamilton Health Sciences, and the REWIND study chair. "Globally, over 415 million people have type 2 diabetes, which is itself a cardiovascular risk factor. However, only about one third have established cardiovascular disease, which is why this new indication, and the supporting evidence, is important for the millions of people in the U.S. living with diabetes."

"For the first time, health care providers can prescribe a diabetes medicine proven to significantly reduce the risk of experiencing a cardiovascular event for people with type 2 diabetes with and without established cardiovascular disease," said Sherry Martin M.D., vice president, medical affairs, Lilly. "Trulicity can help people achieve their A1C goals and protect them from experiencing a cardiovascular event with a once-weekly, easy-to-use treatment option."

Trulicity has been available in the U.S. since 2014 and is the number one prescribed GLP-1 RA. In addition to its proven glycemic efficacy and easy-to-use device**, Trulicity can now be prescribed to help people with type 2 diabetes reduce their risk of CV events.

About the REWIND Study

REWIND (Researching cardiovascular Events with a Weekly INcretin in Diabetes) was a multicenter, randomized, double-blind, placebo-controlled trial designed to assess the effect of Trulicity 1.5 mg, a weekly glucagon-like peptide 1 receptor agonist (GLP-1 RA), compared to placebo, both added to standard of care (according to local standard of care guidelines), on cardiovascular (CV) events in adults with type 2 diabetes. The primary CV outcome was the first occurrence of MACE (the composite of CV death or nonfatal myocardial infarction or nonfatal stroke). Secondary outcomes include each component of the primary composite CV outcome, a composite clinical microvascular outcome comprising retinal or renal disease, hospitalization for unstable angina, heart failure requiring hospitalization or an urgent heart failure visit, and all-cause mortality. The 9,901 participants from 24 countries had a mean duration of diabetes of 10.5 years and a median baseline A1C of 7.2 percent. While all participants had CV risk factors, only 31.5 percent of the study participants had established CV disease. Prior (or established) cardiovascular disease in REWIND was defined as prior myocardial infarction, prior ischemic stroke, prior unstable angina, prior revascularization (coronary, carotid, or peripheral), prior hospitalization for ischemia-related events (unstable angina or myocardial ischemia on imaging, or need for percutaneous coronary intervention), or prior documented myocardial ischemia.

The REWIND trial's international scope, high proportion of women, high proportion of people without established cardiovascular disease and inclusion of participants with a lower mean baseline A1C suggest that the findings will be directly relevant to the typical type 2 diabetes patient seen in general practice.

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

Approximately 30 million Americans¹ and an estimated 463 million adults worldwide have diabetes.² 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.¹ 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](https://twitter.com/LillyDiabetes) and Facebook: [LillyDiabetesUS](https://www.facebook.com/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 lilly.com and lilly.com/newsroom. P-LLY

*Primary prevention: Reducing the risk of atherosclerotic cardiovascular disease by preventing or managing risk factors. Secondary prevention: Reducing the risk of another event in people who have had a serious CV incident or procedure.

**In a study, 94% of people said it was easy to use.

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Trulicity (dulaglutide) as a treatment for type 2 diabetes and for the reduction of cardiovascular events and its safety profile 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 study findings to date, that Trulicity will receive additional 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. Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2017.
2. International Diabetes Federation. *IDF Diabetes Atlas, 9th edn*. Brussels, Belgium. Available at: <http://www.diabetesatlas.org>.

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