FDA approves Lilly's Mounjaro (tirzepatide) to reduce cardiovascular risk in adults with type 2 diabetes

August 28, 2026

Mounjaro is the first and only GIP and GLP-1 receptor agonist proven to lower heart attack, stroke or cardiovascular death risk in adults with type 2 diabetes at high risk for these events – in addition to its established A1C and weight loss benefits

It is estimated that as many as one in three adults in the U.S. with type 2 diabetes have undetected cardiovascular disease[1]

INDIANAPOLIS, Aug. 28, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Food and Drug Administration (FDA) approved Mounjaro (tirzepatide), a dual GIP and GLP-1 hormone receptor agonist, to lower the risk of major adverse cardiovascular (CV) events (MACE), including CV death, non-fatal heart attack, or non-fatal stroke in adults with type 2 diabetes who are at high risk for these events. Mounjaro is already approved as an adjunct to diet and exercise to improve blood sugar in adults and children 10 years of age and older with type 2 diabetes.

"For people with type 2 diabetes, heart disease is the leading cause of death, and Mounjaro – the #1 most prescribed branded type 2 diabetes medicine for adults in the U.S. – now gives them a proven way to lower that risk, adding to the strong foundation it has already built in A1C and weight," said Kenneth Custer, Ph.D., executive vice president and president, Lilly Cardiometabolic Health. "We set a higher bar by testing Mounjaro against a GLP-1 medicine with proven cardiovascular benefit, one that reflects the depth of evidence Lilly continues to build in this field."

The approval was based on results from SURPASS-CVOT, the first cardiovascular outcomes trial comparing two incretin medicines head-to-head rather than against a placebo, and the largest and longest tirzepatide study to date, enrolling more than 13,000 participants across 30 countries over more than four and a half years. In the trial, Mounjaro demonstrated non-inferiority to Trulicity (dulaglutide), a GLP-1 treatment with established cardiovascular benefit, with an 8% lower rate of cardiovascular death, heart attack or stroke (MACE-3). The estimated hazard ratio for time to first MACE was 0.92 (95.3% CI: 0.83, 1.01) for Mounjaro compared to Trulicity (dulaglutide).

"Heart health deserves attention throughout the course of treatment, not just after a serious cardiovascular event," said David A. D'Alessio, M.D., study co-author and director of the Division of Endocrinology and Metabolism at Duke University School of Medicine. "While a large portion of type 2 diabetes care is focused on glucose control, mitigating cardiovascular risk is essential and can be overlooked. This approval gives patients a medicine that reduces the risk of cardiovascular events and supports metabolic health at the same time."

The safety and tolerability of Mounjaro were generally consistent with its established profile. The most commonly reported adverse events in SURPASS-CVOT for Mounjaro were gastrointestinal-related, generally mild-to-moderate in severity, and occurred primarily during the dose-escalation period. Please see **Indications and Safety Summary with Warnings** below and full **Prescribing Information** and **Medication Guide**.

For more information about Mounjaro, please visit www.Mounjaro.lilly.com.

About Mounjaro (tirzepatide)
Mounjaro (tirzepatide), the #1 prescribed branded type 2 diabetes medicine for adults in the U.S., is an injectable medicine for adults and children 10 years of age and older with type 2 diabetes used along with diet and exercise to improve blood sugar (glucose). In adults with type 2 diabetes who are at high risk for cardiovascular events, Mounjaro is also indicated to lower the risk of major adverse cardiovascular (CV) events (MACE), including CV death, non-fatal heart attack, or non-fatal stroke. As the first and only FDA-approved GIP and GLP-1 receptor agonist, Mounjaro is a single molecule that activates the body's receptors for GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1).

About Trulicity (dulaglutide)
Trulicity is a once-weekly injectable medicine for adults and children 10 years of age and older with type 2 diabetes that is used with diet and exercise to improve blood sugar (glucose). Trulicity is also used in adults with type 2 diabetes to reduce the risk of major cardiovascular events such as death, heart attack, or stroke, in people with established cardiovascular disease or multiple cardiovascular risk factors.

About SURPASS-CVOT
SURPASS-CVOT (Cardiovascular Outcomes Trial; NCT04255433) was an event-driven, randomized, double-blind, parallel group Phase 3 trial evaluating the efficacy and safety of Mounjaro (tirzepatide) compared with Trulicity (dulaglutide) in adults with type 2 diabetes and established atherosclerotic cardiovascular disease (ASCVD), which lasted approximately five years (with a median follow-up of four years). In the trial, 13,299 participants were randomized 1:1 across 640 sites in 30 countries to receive Mounjaro (15 mg or the maximum tolerated dose) or Trulicity (1.5 mg) administered subcutaneously once weekly. The primary objective of the trial was to demonstrate that Mounjaro provided a non-inferior reduction in the risk of major adverse cardiovascular events (MACE-3) — a composite of cardiovascular death, heart attack or stroke — compared to Trulicity. Over a median follow-up of 210.1 weeks, Mounjaro was non-inferior to dulaglutide for reducing the occurrence of MACE-3. Superiority to dulaglutide was not established. Full results from SURPASS-CVOT were published in *The New England Journal of Medicine (NEJM)*. Data from the trial has been included in Mounjaro's product information in the European Union, and regulatory submissions based on the trial are under review in additional markets.

INDICATIONS AND SAFETY SUMMARY WITH WARNINGS

Mounjaro® (mown-JAHR-OH) is an injectable prescription medicine used along with diet and exercise to improve blood sugar (glucose) in adults and children 10 years of age and older with type 2 diabetes and to reduce the risk of major cardiovascular events such as heart attack, stroke, or death in adults with type 2 diabetes who are at high risk for these events.

- It is not known if Mounjaro is safe and effective for use in children under 10 years of age.

Warnings - Mounjaro may cause tumors in the thyroid, including thyroid cancer. Watch for possible symptoms, such as a lump or swelling in the neck, hoarseness, trouble swallowing, or shortness of breath. If you have any of these symptoms, tell your healthcare provider.

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

Mounjaro may cause serious side effects, including:

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

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Mounjaro with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. **Signs and symptoms of low blood sugar may include** dizziness or light-headedness, sweating, confusion or drowsiness, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability, or mood changes, hunger, weakness and feeling jittery.

Serious allergic reactions. Stop using Mounjaro and get medical help right away if you have any 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, and very rapid heartbeat.

Dehydration leading to kidney problems. Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration. Tell your healthcare provider right away if you have nausea, vomiting, or diarrhea that does not go away.

Severe stomach problems. Stomach problems, sometimes severe, have been reported in people who use Mounjaro. Tell your healthcare provider if you have stomach problems that are severe or will not go away.

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

Gallbladder problems. Gallbladder problems have happened in some people who use Mounjaro. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include pain in your upper stomach (abdomen), fever, yellowing of skin or eyes (jaundice), and clay-colored stools.

Food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sleepiness (deep sedation). Mounjaro may increase the chance of food getting into your lungs during surgery or other procedures. Tell all your healthcare providers that you are taking Mounjaro before you are scheduled to have surgery or other procedures.

Common side effects
The most common side effects of Mounjaro include nausea, diarrhea, decreased appetite, vomiting, constipation, indigestion, and stomach (abdominal) pain. These are not all the possible side effects of Mounjaro. Talk to your healthcare provider about any side effect that bothers you or doesn't go away.

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

Before using Mounjaro

- **Your healthcare provider should show you how to use Mounjaro before you use it for the first time.**
- **Talk to your healthcare provider about low blood sugar and how to manage it.**
- **If you take birth control pills by mouth, talk to your healthcare provider before you use Mounjaro. Birth control pills may not work as well while using Mounjaro.** Your healthcare provider may recommend another type of birth control for 4 weeks after you start Mounjaro and for 4 weeks after each increase in your dose of Mounjaro.

Review these questions with your healthcare provider:
❑ Do you have other medical conditions, including problems with your pancreas, or severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems digesting food?
❑ Do you take other diabetes medicines, such as insulin or sulfonylureas?
❑ Do you have a history of diabetic retinopathy?
❑ Are you scheduled to have surgery or other procedures that use anesthesia or deep sleepiness (deep sedation)?
❑ Are you pregnant, plan to become pregnant, breastfeeding, or plan to breastfeed? It is not known if Mounjaro will harm your unborn baby. Mounjaro may pass into your breast milk.
❑ Do you take any other prescription medicines or over-the-counter drugs, vitamins, or herbal supplements?

How to take

- Read the **Instructions for Use** that come with Mounjaro.
- Use Mounjaro exactly as your healthcare provider says.
- A caregiver may give you Mounjaro injections, or you may self-inject if a healthcare provider determines that it is appropriate.

- Inject Mounjaro under the skin (subcutaneously) of your stomach (abdomen), thigh, or another person should inject in the back of the upper arm. **Do not** inject Mounjaro into a muscle (intramuscularly) or vein (intravenously).
- **Use Mounjaro 1 time each week, at any time of the day.**
- **Do not** mix insulin and Mounjaro together in the same injection.
- You may give an injection of Mounjaro and insulin in the same body area (such as your stomach area), but not right next to each other.
- Change (rotate) your injection site with each weekly injection. **Do not** use the same site for each injection.
- If you take too much Mounjaro, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

Learn more
Mounjaro is a prescription medicine available as a pre-filled single-dose pen in 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg per 0.5 mL injection. For more information, call 1-800-LillyRX (800-545-5979) or go to **www.mounjaro.lilly.com.**

This summary provides basic information about Mounjaro 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 healthcare provider. Be sure to talk to your healthcare provider about Mounjaro and how to take it. Your healthcare provider is the best person to help you decide if Mounjaro is right for you.

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INDICATION[S] AND SAFETY SUMMARY WITH WARNINGS

Trulicity® (Trū-li-si-tee) is for adults and children 10 years of age and older with type 2 diabetes used along with diet and exercise to improve blood sugar (glucose). Trulicity is also used in adults with type 2 diabetes to reduce the risk of major cardiovascular events (problems having to do with the heart and blood vessels) such as death, heart attack, or stroke in people who have heart disease or multiple cardiovascular risk factors.

- It is not known if Trulicity is safe and effective to lower blood sugar (glucose) in children under 10 years of age.
- Trulicity is given through an injection (needle). You take it once a week by injecting it under the skin of your stomach, thigh, or upper arm.

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 any of these symptoms, tell your healthcare provider.

- 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 healthcare provider how to recognize the serious side effects below and what to do if you think you have one:

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

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use TRULICITY with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin.

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.

Dehydration leading to kidney problems. Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration. Tell your healthcare provider right away if you have nausea, vomiting, or diarrhea that does not go away.

Severe stomach problems. Stomach problems, sometimes severe, have been reported in people who use Trulicity. Tell your healthcare provider if you have stomach problems that are severe or will not go away.

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

Gallbladder problems. Gallbladder problems have happened in some people who take Trulicity. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include pain in your upper stomach (abdomen), fever, yellowing of skin or eyes (jaundice), clay-colored stools.

Food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sleepiness (deep sedation). Trulicity may increase the chance of food getting into your lungs during surgery or other procedures. Tell all your healthcare providers that you are taking Trulicity before you are scheduled to have surgery or other procedures.

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

These are not all the possible side effects of Trulicity.

Tell your healthcare provider 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 healthcare provider about low blood sugar and how to manage it.**

Review these questions with your healthcare provider:
❑ Do you have other medical conditions, including problems with your pancreas, kidneys, liver, or stomach, or have a history of diabetic retinopathy (vision problems related to diabetes)?
❑ Do you take other diabetes medicines, such as insulin or sulfonylureas?
❑ Are you scheduled to have surgery or other procedures that use anesthesia or deep sleepiness (deep sedation)?
❑ Are you pregnant or plan to become pregnant or breastfeeding or plan to breastfeed?
❑ Do you take any other prescription medicines or over-the-counter drugs, vitamins, or herbal supplements?

How to take

- Read the Instructions for Use that come with Trulicity.
- Use Trulicity exactly as your healthcare provider says.
- Inject Trulicity under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm. Do not inject Trulicity into a muscle (intramuscularly) or vein (intravenously).
- 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 Poison Helpline at 1-800-222-1222 or go to the nearest hospital emergency room right away.

Learn more
Trulicity is a prescription medicine available as a pre-filled single-dose pen in 0.75 mg,1.5 mg, 3 mg, or 4.5 mg per 0.5 mL injection. For more information, call 1-800-LillyRx (1-800-545-5979) or go to www.trulicity.lilly.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 healthcare provider. Be sure to talk to your healthcare provider about Trulicity and how to take it. Your healthcare provider is the best person to help you decide if Trulicity is right for you.

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Endnotes

1. Fang M, Wang D, Tang O, et al. Subclinical cardiovascular disease in US adults with and without diabetes. *J Am Heart Assoc*. 2023;12(11): e029083. doi:10.1161/JAHA.122.029083.

About Lilly
Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for 150 years, and today our medicines help tens of millions of people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges: redefining diabetes care; treating obesity and curtailing its most devastating long-term effects; advancing the fight against Alzheimer's disease; providing solutions to some of the most debilitating immune system disorders; and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/news, or follow us on Facebook, Instagram, and LinkedIn. P-LLY

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Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Mounjaro as a treatment for adults with type 2 diabetes and who are at high risk for cardiovascular events and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and

commercialization. Among other things, there is no guarantee that future study results will be consistent with study results to date, that Mounjaro will receive additional regulatory approvals, or that Lilly will execute its strategy as planned. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's 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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