



Lilly's retatrutide delivered greater A1C reduction and more than double the weight loss of Ozempic's highest approved dose in head-to-head trial

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In adults with type 2 diabetes, retatrutide lowered A1C by an average of 2.2% vs. 1.8% with Ozempic 2 mg at 80 weeks

Participants taking retatrutide lost an average of 44 lbs to 47 lbs (20% to 21%) vs. 21 lbs (9%) with Ozempic 2 mg at 80 weeks

TRANSCEND-T2D-2 marks the sixth Phase 3 trial in which retatrutide has delivered powerful efficacy, reinforcing its potential to transform cardiometabolic care

INDIANAPOLIS, Oct 28, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY), the maker of Mounjaro (tirzepatide) and Foundayo (orforglipron), today announced positive topline results from TRANSCEND-T2D-2, a head-to-head Phase 3 trial comparing retatrutide with injectable Ozempic 2 mg in adults with type 2 diabetes. At 80 weeks, retatrutide met the primary and all key secondary endpoints, delivering greater A1C reduction and substantially more weight loss than Ozempic.^{1,2}

Kenneth Custer, Ph.D., Executive Vice President and President of Lilly Cardiometabolic Health: "Head-to-head trials show patients and physicians how a potential new medicine compares with treatments that are available and reimbursed today. In TRANSCEND-T2D-2, the first Phase 3 trial comparing retatrutide with another incretin medicine, retatrutide delivered greater A1C reduction and more than double the weight loss of the highest approved dose of Ozempic for type 2 diabetes. Based on these results and those from across our Phase 3 program, we believe retatrutide, if approved, could shift the treatment paradigm for people living with type 2 diabetes, obesity and related cardiometabolic conditions."

In the TRANSCEND-T2D-2 trial, both doses of retatrutide lowered A1C by an average of 2.2% compared to 1.8% with Ozempic at 80 weeks. Participants taking retatrutide lost an average of 44.3 lbs (19.5%; 9 mg) and 47.4 lbs (20.9%; 12 mg) compared to 20.9 lbs (9.4%) with Ozempic. Retatrutide also delivered greater improvements than Ozempic across certain cardiovascular risk factors, including non-HDL cholesterol, triglycerides and systolic blood pressure.¹

TRANSCEND-T2D-2 Efficacy Estimand Results at 80 Weeks

Primary Endpoint			
	Retatrutide 9 mg	Retatrutide 12 mg	Ozempic 2 mg
Change in A1C from avg. baseline of 8.3%	-2.2% ^{i,ii}	-2.2% ⁱⁱⁱ	-1.8 %
Key Secondary Endpoint			
Percent change in body weight from avg. baseline of 102.4 kg (225.8 lbs; BMI of 36.8 kg/m ²)	-19.5% ⁱⁱⁱ (-20.1 kg; -44.3 lbs)	-20.9% ⁱⁱⁱ (-21.5 kg; -47.4 lbs)	-9.4% (-9.5 kg; -20.9 lbs)

ⁱNominal $p < 0.001$ vs. Ozempic 2 mg

ⁱⁱNoninferiority for change in A1C with retatrutide 9 mg vs. Ozempic 2 mg was a key secondary endpoint.

ⁱⁱⁱ $p < 0.001$ vs. Ozempic 2 mg; family-wise type 1 error controlled for superiority.

In TRANSCEND-T2D-2, the most common adverse events with retatrutide (9 mg, 12 mg vs. Ozempic) were diarrhea (28.3%, 32.7% vs. 26.4%), nausea (21.2%, 23.8% vs. 21.3%), constipation (14.2%, 13.1% vs. 19.8%), vomiting (10.2%, 15.0% vs. 13.2%) and dyspepsia (10.4%, 8.5% vs. 11.6%). The incidence of dysesthesia with retatrutide (9 mg, 12 mg vs. Ozempic) was 4.8%, 6.5% vs. 2.7%, while the incidence of urinary tract infections was 5.8%, 4.2% vs. 5.8%. The majority of these events were mild-to-moderate and typically resolved during treatment. Treatment discontinuation rates due to adverse events were 4.8%, 7.9% vs. 2.7% with retatrutide 9 mg and 12 mg vs. Ozempic, respectively.

Detailed results from TRANSCEND-T2D-2 will be presented at a future medical meeting and published in a peer-reviewed journal.

Frequently Asked Questions

1. Why are head-to-head trials important?

Head-to-head trials compare a potential new medicine directly with a treatment already in use, giving patients and physicians evidence that reflects the choices they face every day. As the number of effective treatments for type 2 diabetes and obesity has grown, Lilly believes these direct comparisons are increasingly important.

2. Why did TRANSCEND-T2D-2 compare retatrutide with Ozempic 2 mg?

TRANSCEND-T2D-2 compared retatrutide with injectable Ozempic 2 mg because it is the highest approved dose, making it a meaningful point of comparison. In the trial, retatrutide delivered greater A1C reduction and more than double the weight loss of Ozempic. Lilly is also comparing retatrutide head-to-head with tirzepatide in TRIUMPH-5, an ongoing Phase 3 trial in adults with obesity with or without type 2 diabetes.

3. How did retatrutide compare with Ozempic?

In TRANSCEND-T2D-2, both doses of retatrutide delivered greater A1C reduction and more than double the weight loss of Ozempic 2 mg at 80 weeks. Participants taking retatrutide lowered their A1C by an average of 2.2% compared to 1.8% with Ozempic and lost an average of 44.3 lbs (19.5%; 9 mg) and 47.4 lbs (20.9%; 12 mg) compared to 20.9 lbs (9.4%) with Ozempic. The most common adverse events with retatrutide were gastrointestinal-related. Treatment discontinuation rates due to adverse events were 4.8% (9 mg) and 7.9% (12 mg) with retatrutide, compared to 2.7% with Ozempic.

4. What could these results mean for people with type 2 diabetes?

In TRANSCEND-T2D-2, people taking the highest dose of retatrutide lost an average of 47.4 lbs (20.9%), more than double the weight loss seen with Ozempic, along with greater A1C reduction. In TRIUMPH-2, people with type 2 diabetes and obesity taking the highest dose lost an average of 49.6 lbs (20.8%). Weight loss has historically been more difficult for people living with type 2 diabetes, and Lilly believes that, if approved, retatrutide could shift how the disease is treated.

5. Is anyone legally allowed to sell retatrutide to patients?

No. Retatrutide is an investigational molecule that has not been approved by FDA or any regulatory organization anywhere in the world. Anyone purporting to sell retatrutide to consumers is breaking the law.

About retatrutide

Retatrutide is an investigational, once-weekly, triple hormone receptor agonist. Retatrutide is a single molecule that activates the body's receptors for glucose-dependent insulinotropic polypeptide (GIP), glucagon-like peptide-1 (GLP-1), and glucagon. Lilly is studying retatrutide in several Phase 3 clinical trials to evaluate its potential efficacy and safety in obesity and overweight with at least one weight-related medical problem, type 2 diabetes, knee osteoarthritis pain, moderate-to-severe obstructive sleep apnea, chronic low back pain, cardiovascular outcomes, and metabolic dysfunction-associated steatotic liver disease. Retatrutide is an investigational molecule that cannot be legally sold or marketed for human use.

About TRANSCEND-T2D-2 and TRANSCEND clinical trial program

TRANSCEND-T2D-2 (NCT06260722) is a Phase 3, randomized, open-label trial comparing once-weekly retatrutide (9 mg and 12 mg) with once-weekly Ozempic 2 mg in 1,298 adults with type 2 diabetes inadequately controlled with metformin, with or without an SGLT2 inhibitor. Participants with a baseline A1C of 7.0% to 10.5% were randomized 2:2:1 to retatrutide 9 mg, retatrutide 12 mg or Ozempic 2 mg. The primary objective was to demonstrate that retatrutide 12 mg is noninferior to Ozempic 2 mg in A1C reduction at 80 weeks. Retatrutide was initiated at 2 mg and increased every four weeks to the 9 mg or 12 mg target dose. TRANSCEND-T2D-2 also includes an extension period in which approximately 650 participants continue treatment with retatrutide for an additional 24 weeks to evaluate long-term efficacy and safety.

The TRANSCEND-T2D Phase 3 clinical trial program is evaluating the safety and efficacy of retatrutide for the treatment of adults with type 2 diabetes across three global registrational trials. The program, which began in 2024, has enrolled more than 2,050 participants.

Endnotes and References:

1. All comparisons of retatrutide vs. Ozempic 2 mg were controlled for family-wise type 1 error, except superiority of retatrutide 9 mg vs. Ozempic 2 mg in change in A1C and in systolic blood pressure, which were prespecified secondary endpoints and showed nominal statistical significance. A1C noninferiority for retatrutide 9 mg vs. Ozempic 2 mg was met under family-wise type 1 error control as a key secondary endpoint.
2. All data included in this press release are for the efficacy estimand. The efficacy estimand represents efficacy had all randomized participants remained on study intervention (with possible dose interruptions and modifications) for 80 weeks without initiating additional antihyperglycemic medication (>14 days of use).

FOUNDAYO INDICATION AND SAFETY SUMMARY WITH WARNINGS

Foundayo (fown-DAY-oh) is a prescription medicine used with a reduced-calorie diet and increased physical activity to help adults with obesity, or some adults with overweight who also have weight-related medical problems, to lose excess body weight and keep the weight off.

- Foundayo should not be used with other GLP-1 receptor agonist medicines.
- It is not known if Foundayo is safe and effective for use in children.

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

Foundayo may cause serious side effects, including:

Inflammation of the pancreas (pancreatitis). Stop taking Foundayo 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.

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

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.

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Foundayo with medicines that can cause low blood sugar, such as an insulin or sulfonylurea. 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, mood changes, hunger, weakness, or feeling jittery.

Serious allergic reactions. Stop using Foundayo 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, or very rapid heartbeat.

Changes in vision in patients with type 2 diabetes. Tell your healthcare provider if you have changes in vision during treatment with Foundayo.

Gallbladder problems. Gallbladder problems have happened in some people who use Foundayo. 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), or clay-colored stools.

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

Common side effects

The most common side effects of Foundayo include nausea, constipation, diarrhea, vomiting, indigestion, stomach (abdominal) pain, headache, swollen belly, feeling tired, belching, heartburn, gas, and hair loss. These are not all the possible side effects of Foundayo. Talk to your healthcare provider about any side effect that bothers you or doesn't go away.

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 taking Foundayo

- **Tell your healthcare provider about all the medicines you take.** Foundayo may affect the way some medicines work, and some medicines may affect the way Foundayo works.
- **Pregnancy Exposure Registry:** There will be a pregnancy exposure registry for women who have taken Foundayo during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry, or you may contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979).
- **If you take birth control pills by mouth, talk to your healthcare provider before you take Foundayo. Birth control pills may not work as well while taking Foundayo.** Your healthcare provider may recommend another type of birth control for 30 days after starting Foundayo and for 30 days after each dose increase of Foundayo.
- **Talk to your healthcare provider about low blood sugar and how to manage it.** Tell your healthcare provider if you are taking medicines to treat diabetes including an insulin or sulfonylurea.

Review these questions with your healthcare provider:

- ☐ Do you have other medical conditions, including problems with your pancreas or kidneys, or severe problems with your liver, severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems digesting food?
- ☐ 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 or plan to become pregnant? Foundayo may harm your unborn baby.
- ☐ Are you breastfeeding or plan to breastfeed? Breastfeeding is not recommended during treatment with Foundayo.
- ☐ Do you take any other prescriptions or over-the-counter medicines, vitamins, or herbal supplements?

How to take

- Take Foundayo exactly as your healthcare provider tells you to.
- Use Foundayo with a reduced-calorie diet and increased physical activity.
- Take Foundayo by mouth 1 time each day, with or without food.
- Swallow tablets whole. Do not break, crush, or chew the tablet.
- If you miss a dose, take it as soon as possible. **Do not take 2 doses of Foundayo in the same day.**
- **Do not take more than 1 tablet per day.**
- If you miss taking Foundayo for 7 or more days in a row, call your healthcare provider to talk about how to restart your treatment.
- If you take too much Foundayo, 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

Foundayo is a prescription medicine available in 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, or 17.2 mg oral tablets. For more information, call 1-800-545-5979 or go to foundayo.lilly.com.

This summary provides basic information about Foundayo 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 Foundayo and how to take it. Your doctor is the best person to help you decide if Foundayo is right for you.

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MOUNJARO 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.

- o 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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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](https://www.facebook.com/Lilly), [Instagram](https://www.instagram.com/Lilly), and [LinkedIn](https://www.linkedin.com/company/Lilly). 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 retatrutide as a potential treatment for adults with type 2 diabetes, and the timeline for future readouts, presentations and other milestones relating to retatrutide and its clinical trials 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 planned or ongoing studies will be completed as planned, that future study results will be consistent with expectations or study results to date, that retatrutide will prove to be a safe and effective treatment for type 2 diabetes, obesity or other potential indications, that retatrutide will receive regulatory approval, or that Lilly will execute its strategy as expected. 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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