



Lilly's oral GLP-1, Foundayo (orforglipron), was associated with significant reductions in predicted long-term risk of type 2 diabetes and cardiovascular disease

October 1, 2026

In post-hoc analyses of ATTAIN-1, Foundayo 17.2 mg was associated with a predicted 57% and 18% reduction in risk of type 2 diabetes and cardiovascular disease vs. placebo

Combined with recent research on the savings tied to weight loss, these findings suggest Foundayo could help reduce long-term spending for patients and healthcare systems

INDIANAPOLIS, Oct. 1, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY), the maker of Zepbound (tirzepatide), today announced results from post-hoc analyses of ATTAIN-1 showing that Foundayo was associated with significant reductions in predicted 10-year risk of type 2 diabetes and cardiovascular disease in adults with obesity or overweight with a weight-related medical problem. Obesity is strongly associated with an increased risk of developing both cardiovascular disease and type 2 diabetes.¹ Through its proven benefit in weight loss and its ability to improve certain cardiovascular risk factors like blood sugar, blood pressure and cholesterol, Foundayo may be a meaningful treatment option for the more than 100 million U.S. adults living with obesity.² The findings of these analyses were published in *Diabetes, Obesity and Metabolism*.

"For many people living with obesity or overweight, the concern isn't just what the scale says today, it's whether their future could include type 2 diabetes or heart disease," said Thomas Seck, M.D., senior vice president of product development, Lilly Cardiometabolic Health. "These additional analyses of ATTAIN-1 show that Foundayo was associated with a lower predicted long-term risk of both conditions, in addition to meaningful weight loss. We've also seen evidence that treating obesity and reducing the risk of its downstream consequences, like cardiovascular disease and type 2 diabetes, can meaningfully lower healthcare costs.^{3,4,5} That gives us real optimism about what long-term Foundayo use could mean, both for patients and for the broader healthcare system."

In these analyses, modeling showed that Foundayo was associated with clinically meaningful improvements in predicted 10-year risk of type 2 diabetes and cardiovascular disease across all three doses.⁶ At 72 weeks, participants taking Foundayo 5.5 mg, 9 mg and 17.2 mg showed an estimated 45.0%, 50.0% and 57.0% reduction, respectively, in predicted type 2 diabetes risk versus placebo.^{7,8} Participants taking Foundayo 17.2 mg also showed an estimated 18.0% reduction in predicted cardiovascular disease risk versus placebo.

ATTAIN-1 Post-Hoc Analyses: Change in Predicted 10-Year Cardiometabolic Risk at 72 Weeks

	Foundayo 5.5 mg	Foundayo 9 mg	Foundayo 17.2 mg	Placebo
Type 2 diabetes riskⁱ				
Predicted 10-year type 2 diabetes risk at baseline	16.4 %	16.0 %	17.1 %	17.3 %
Change in predicted 10-year type 2 diabetes risk at 72 weeks	-8.0 %	-8.8 %	-9.8 %	-1.7 %
Estimated type 2 diabetes risk reduction vs. placebo ⁱⁱ	45% (HR = 0.55) (95% CI 0.52, 0.60)	50% (HR = 0.50) (95% CI 0.47, 0.54)	57% (HR = 0.43) (95% CI 0.40, 0.47)	—
Cardiovascular disease riskⁱⁱⁱ				
Predicted 10-year cardiovascular disease risk at baseline	8.5 %	8.5 %	8.7 %	8.9 %
Change in predicted 10-year cardiovascular disease risk at 72 weeks	-0.6 %	-0.7 %	-1.0 %	0.6 %
Estimated cardiovascular disease risk reduction vs. placebo ⁱⁱ	13% (HR = 0.87) (95% CI 0.83, 0.90)	15% (HR = 0.85) (95% CI 0.82, 0.89)	18% (HR = 0.82) (95% CI 0.79, 0.86)	—

ⁱType 2 diabetes risk was estimated using the Cardiometabolic Disease Staging (CMDSt) risk engine.

ⁱⁱEstimated risk reduction versus placebo is approximated based on the model-based hazard ratio (HR); placebo was the reference group.

ⁱⁱⁱCardiovascular disease risk was estimated using the BMI-based Framingham risk engine.

About Foundayo

Foundayo (orforglipron) is FDA-approved for adults with obesity, or some adults with overweight who also have weight-related medical problems to reduce excess body weight and maintain weight reduction long term, alongside a reduced-calorie diet and increased physical activity. Foundayo is a once-daily small molecule (non-peptide) oral glucagon-like peptide-1 receptor agonist that can be taken any time of the day without restrictions on food and water intake. Orforglipron was discovered by Chugai Pharmaceutical Co., Ltd. and licensed by Lilly in 2018. In addition to chronic weight management, orforglipron is being studied as a potential treatment for type 2 diabetes, obstructive sleep apnea, osteoarthritis knee pain, hypertension, peripheral artery disease and stress urinary incontinence.

About ATTAIn-1 and the ATTAIn clinical trial program

ATTAIn-1 (NCT05869903) is a Phase 3, 72-week, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of Foundayo 5.5 mg, 9 mg and 17.2 mg as a monotherapy to placebo in adults with obesity, or overweight with at least one of the following comorbidities: hypertension, dyslipidemia, obstructive sleep apnea or cardiovascular disease, who did not have diabetes. The trial is the first Phase 3 study of this patient population in which treatment was evaluated as an adjunct to exercise and a balanced, healthy diet rather than a reduced-calorie diet. The trial randomized 3,127 participants across the U.S., Brazil, China, India, Japan, South Korea, Puerto Rico, Slovakia, Spain and Taiwan in a 3:3:3:4 ratio to receive either 5.5 mg, 9 mg or 17.2 mg Foundayo or placebo. The primary objective of the study was to demonstrate that Foundayo (5.5 mg, 9 mg or 17.2 mg) is superior to placebo in body weight reduction from baseline after 72 weeks in people with a BMI ≥ 30.0 kg/m² or a BMI ≥ 27.0 kg/m² with at least one weight-related comorbidity and a history of at least one self-reported unsuccessful dietary effort to lose body weight.

All participants in the Foundayo treatment arms started the study at a dose of Foundayo 0.8 mg once-daily and then increased the dose in a step-wise approach at four-week intervals to their final randomized maintenance dose of 5.5 mg (via steps at 0.8 mg and 2.5 mg), 9 mg (via steps at 0.8 mg, 2.5 mg and 5.5 mg) or 17.2 mg (via steps at 0.8 mg, 2.5 mg, 5.5 mg and 14.5 mg). The trial was conducted using an investigational formulation of Foundayo at dosages equivalent to Foundayo tablets.

The ATTAIn Phase 3 global clinical development program for orforglipron enrolled more than 4,500 people with obesity or overweight across two global registration trials (ATTAIn-1 & ATTAIn-2).

Endnotes and References

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6. D'Agostino Sr RB, Vasan RS, Pencina MJ, Wolf PA, Cobain M, Massaro JM, Kannel WB. General cardiovascular risk profile for use in primary care: the Framingham Heart Study. *Circulation*. 2008;117(6):743-53.
7. Guo F, Garvey WT. Development of a weighted cardiometabolic disease staging (CMDS) system for the prediction of future diabetes. *The Journal of Clinical Endocrinology & Metabolism*. 2015;100(10):3871-7.
8. Wilkinson L, Yi N, Mehta T, Judd S, Garvey WT. Development and validation of a model for predicting incident type 2 diabetes using quantitative clinical data and a Bayesian logistic model: a nationwide cohort and modeling study. *PLoS medicine*. 2020;17(8):e1003232.

U.S. 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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U.S. ZEPBOUND INDICATIONS AND SAFETY SUMMARY WITH WARNINGS

Zepbound® (ZEHP-bownd) is an injectable 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.
- moderate-to-severe obstructive sleep apnea (OSA) and obesity to improve their OSA.

Zepbound contains tirzepatide and should not be used with other tirzepatide-containing products or any GLP-1 receptor agonist medicines. It is not known if Zepbound is safe and effective for use in children.

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

KwikPen®: Do not share your KwikPen with other people, even if the pen needle has been changed. You may give other people a serious infection or get a serious infection from them.

Zepbound may cause serious side effects, including:

Severe stomach problems. Stomach problems, sometimes severe, have been reported in people who use Zepbound. 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.

Gallbladder problems. Gallbladder problems have happened in some people who use Zepbound. 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.

Inflammation of the pancreas (pancreatitis). Stop using Zepbound 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. You may feel the pain from your abdomen to your back.

Serious allergic reactions. Stop using Zepbound 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.

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Zepbound with medicines 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, mood changes, hunger, weakness or feeling jittery.

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

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

Common side effects

The most common side effects of Zepbound include nausea, diarrhea, vomiting, constipation, stomach (abdominal) pain, indigestion, injection site reactions, feeling tired, allergic reactions, belching, hair loss, and heartburn. These are not all the possible side effects of Zepbound. 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 using Zepbound

- Your healthcare provider should show you how to use Zepbound before you use it for the first time.
- 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.
- If you take birth control pills by mouth, talk to your healthcare provider before you use Zepbound. Birth control

pills may not work as well while using Zepbound. Your healthcare provider may recommend another type of birth control for 4 weeks after you start Zepbound and for 4 weeks after each increase in your dose of Zepbound.

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 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)?
- ☐ Do you take any other prescription medicines or over-the-counter drugs, vitamins, or herbal supplements?
- ☐ Are you pregnant, plan to become pregnant, breastfeeding, or plan to breastfeed? Zepbound may harm your unborn baby. Tell your healthcare provider if you become pregnant while using Zepbound. Zepbound may pass into your breast milk. You should talk with your healthcare provider about the best way to feed your baby while using Zepbound.

- **Pregnancy Exposure Registry:** There is a pregnancy exposure registry for women who have taken Zepbound 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 call 1-844-524-0039 or email at MILEregistry@thermofisher.com or visit <https://pregnancyregistry.lilly.com/zepbound>.

How to take

- Read the Instructions for Use that come with Zepbound.
- Use Zepbound exactly as your healthcare provider says.
- Use Zepbound with a reduced-calorie diet and increased physical activity.
- Inject Zepbound under the skin (subcutaneously) of your stomach (abdomen), thigh, or have another person inject in the back of the upper arm. **Do not** inject ZEPBOUND into a muscle (intramuscularly) or vein (intravenously).
- **Use Zepbound 1 time each week, at any time of the day.**
- Change (rotate) your injection site with each weekly injection. **Do not** use the same site for each injection.

If you take too much Zepbound, call your healthcare provider, call the Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

Zepbound is approved as a 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg injection.

Learn more

Zepbound is a prescription medicine. For more information, call 1-800-LillyRx (1-800-545-5979) or go to www.zepbound.lilly.com.

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

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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 Foundayo (orforglipron) as a potential treatment for adults with obesity, 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 study results to date, that Foundayo will receive additional regulatory approvals, 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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The Lilly logo is rendered in a bold, 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'.

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