Lilly's Mounjaro (tirzepatide), a GIP/GLP-1 dual receptor agonist, reduced A1C by an average of 2.2% in a Phase 3 trial of children and adolescents with type 2 diabetes

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In SURPASS-PEDS, Mounjaro met the primary and all key secondary endpoints at 30 weeks and showed sustained improvement in glycemic control and continued BMI reduction through the study's 52-week extension

The safety and tolerability profile of Mounjaro was generally consistent with previous adult studies

INDIANAPOLIS, Sept. 17, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced detailed results from SURPASS-PEDS, the first Phase 3 trial to evaluate the safety and efficacy of Mounjaro (tirzepatide), a GIP/GLP-1 dual receptor agonist, in children and adolescents (ages 10 to less than 18) with type 2 diabetes inadequately controlled with metformin, basal insulin or both. At 30 weeks, Mounjaro met the primary and all key secondary endpoints, achieving superior improvements in A1C and body mass index (BMI) compared to placebo. Results from the trial were presented at the European Association for the Study of Diabetes (EASD) Annual Meeting 2025 and simultaneously published in *The Lancet*.

"Youth living with type 2 diabetes often face a more aggressive disease course, and in many instances, first-line treatments like metformin and basal insulin, fail to control their A1C adequately," said Tamara Hannon, M.D., director of the Clinical Diabetes Program, Indiana University School of Medicine and lead trial investigator. "The SURPASS-PEDS results show that Mounjaro delivered significant and clinically meaningful improvements in blood sugar, BMI and fasting serum glucose in pediatric patients. These results offer a promising opportunity to help shift the long-term health trajectory for young people living with this complex condition."

The trial met the primary endpoint of superior A1C reduction with Mounjaro (pooled doses) compared to placebo at 30 weeks, lowering A1C by an average of 2.2% from an average baseline of 8.05% using the efficacy estimand.[1] In a key secondary endpoint, 86.1% of participants randomized to the 10 mg dose of Mounjaro achieved a target A1C of ≤6.5%. In addition, Mounjaro showed clinically meaningful improvements in BMI, a measure that assesses weight changes in children and adolescents, accounting for their growth over time. The 10 mg dose of Mounjaro reduced BMI by 11.2% on average at 30 weeks. Improvements in A1C and BMI reductions continued through 52 weeks in the trial's long-term extension.

Results at 30 weeks					
Primary Endpoint[i]					
		Mounjaro pooled doses		**Placebo**	
Change in A1C from mean baseline of 8.05%	Efficacy estimand	-2.2 %		0.05 %	
	Treatment-regimen estimand[2]	-2.0 %		-0.2 %	
Key Secondary Endpoints[i]					
		Mounjaro 5 mg	**Mounjaro 10 mg**	**Mounjaro pooled doses**	**Placebo**
Change in A1C from mean baseline of 8.05%	Efficacy estimand	-2.2 %	-2.3 %	-	0.05 %
	Treatment-regimen estimand	-1.9 %	-2.2 %	-	-0.2 %
Percentage of participants achieving A1C ≤6.5%	Efficacy estimand	70.8 %	86.1 %	78.6 %	27.8 %
	Treatment-regimen estimand	66.4 %	80.6 %	73.6 %	28.2 %
Percentage change in BMI from mean baseline of 35.3 kg/m^2	Efficacy estimand	-7.4 %	-11.2 %	-9.3 %	-0.4 %
	Treatment-regimen estimand	-6.7 %	-11.1 %	-8.9 %	-0.55 %
Change in BMI-standard deviation score (age and sex matched) from mean baseline of 3.1	Efficacy estimand	-0.50	-0.76	-0.63	-0.09
	Treatment-regimen estimand	-0.45	-0.76	-0.60	-0.09

Change in fasting serum glucose from mean baseline of 152 mg/dL	Efficacy estimand	-35.0 mg/dL	-53.5 mg/dL	-44.2 mg/dL	-7.9 mg/dL
	Treatment-regimen estimand	-35.5 mg/dL	-50.6 mg/dL	-43.0 mg/dL	-6.6 mg/dL

[i] *Controlled for overall Type 1 error.*

"Type 2 diabetes in children and teens is increasing at an alarming rate, yet treatment options are limited, and this patient population remains underserved," said Kenneth Custer, Ph.D., executive vice president and president of Lilly Cardiometabolic Health. "The SURPASS-PEDS results show Mounjaro delivered statistically significant improvements in A1C, BMI and other critical cardiometabolic risk factors, while maintaining a safety profile generally consistent with adult studies. By undertaking this research, we can better support children and adolescents living with this condition."

The overall safety profile of Mounjaro in SURPASS-PEDS was generally consistent with the established incretin class, including previous data from the SURPASS trials. The most common adverse events for participants treated with Mounjaro (5 mg, 10 mg and pooled doses, respectively) were diarrhea (25%, 24% and 25% vs. 6% with placebo), nausea (22%, 18% and 20% vs. 9% with placebo), vomiting (16%, 12% and 14% vs. 3% with placebo), upper abdominal pain (6%, 12% and 9% vs. 9% with placebo), and abdominal pain (16%, 3% and 9% vs. 3% with placebo). These gastrointestinal-related adverse events were all mild-to-moderate in severity and occurred primarily during dose escalation. Overall treatment discontinuation rates due to adverse events were 6% (5 mg), 0% (10 mg) and 3% (pooled doses) for Mounjaro vs. 0% with placebo. No episodes of severe hypoglycemia were observed. The percentage of participants who reported Level 2 hypoglycemia (blood glucose <54 mg/dL) through 30 weeks was 15.4% in Mounjaro groups vs. 5.9% on placebo, a rate consistent with other youth-onset type 2 diabetes trials.

Lilly has submitted the results from SURPASS-PEDS to global regulatory agencies for an expanded indication.

About tirzepatide
Tirzepatide is a once-weekly GIP (glucose-dependent insulinotropic polypeptide) receptor and GLP-1 (glucagon-like peptide-1) dual receptor agonist. Tirzepatide is a single molecule that activates the body's receptors for GIP and GLP-1, which are natural incretin hormones. Both GIP and GLP-1 receptors are found in areas of the human brain important for appetite regulation. Tirzepatide decreases calorie intake, and the effects are likely mediated by affecting appetite. Tirzepatide lowers fasting and postprandial glucose, increases insulin sensitivity, decreases food intake and reduces body weight in patients with type 2 diabetes. Studies of tirzepatide in chronic kidney disease (CKD) and in morbidity/mortality in obesity (MMO) are ongoing.

Tirzepatide has been approved by the U.S. FDA as Mounjaro for adults with type 2 diabetes to improve glycemic control, and as Zepbound for adults with obesity, or some adults who are overweight and also have at least one weight-related medical problem, to lose weight and keep it off. Additionally, Zepbound is FDA-approved to treat adults with moderate-to-severe obstructive sleep apnea and obesity. Tirzepatide is also approved as Mounjaro in some countries outside the U.S. for adults with type 2 diabetes, obesity or those who are overweight who also have a weight-related comorbid condition. Both Mounjaro and Zepbound should be used in combination with diet and exercise.

About SURPASS-PEDS
SURPASS-PEDS (NCT05260021) is a regulator-required, Phase 3, multicenter, randomized, double-blind, placebo-controlled, trial with an open-label extension evaluating the efficacy, safety and pharmacokinetics of Mounjaro (tirzepatide) in children and adolescents (ages 10 to less than 18) with type 2 diabetes inadequately controlled with metformin, basal insulin or both. The trial randomized 99 participants across the U.S., Australia, Brazil, India, Israel, Italy, Mexico and the United Kingdom to receive Mounjaro (up to 5 mg or 10 mg once weekly) or placebo once weekly. The primary objective of the study was to demonstrate that Mounjaro (pooled doses) is superior to placebo in mean change in A1C from baseline after 30 weeks.

In the open-label extension of the trial (week 31 to 52), all participants received Mounjaro. Inclusion criteria for the trial included an A1C of >6.5% to ≤11% at screening, body weight ≥50 kg (110 lbs) and BMI >85th percentile of the general age and gender-matched population for that country or region. Participants in the trial had an average baseline A1C of 8.04%, an average baseline BMI of 35.4 kg/m^2, an average baseline weight of 96.6 kg, an average baseline BMI standard deviation score of 3.11 and a duration of diabetes of 2.4 years.

Endnotes and References

1. The efficacy estimand represents efficacy had all randomized participants remained on study intervention for 30 weeks without initiation of rescue antihyperglycemic medications (>2 weeks of use).
2. The treatment-regimen estimand represents the estimated average treatment effect on all randomized participants regardless of discontinuation of study intervention or initiation of rescue antihyperglycemic medications.

INDICATION AND SAFETY SUMMARY WITH WARNINGS
Mounjaro® (mown-JAHR-OH) is an injectable medicine for adults with type 2 diabetes used along with diet and exercise to improve blood sugar (glucose).

- It is not known if Mounjaro is safe and effective for use in children.

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 vomiting. 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.

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 or 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.
- Inject Mounjaro under the skin (subcutaneously) of your stomach (abdomen), thigh, or 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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INDICATIONS AND SAFETY SUMMARY WITH WARNINGS
Zepbound (ZEHP-bownd) is an injectable prescription medicine that may 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.

It should be used with a reduced-calorie diet and increased physical activity.

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.

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.

Kidney problems (kidney failure). 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.

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 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.

Depression or thoughts of suicide. You should pay attention to changes in your mood, behaviors, feelings or thoughts. Call your healthcare provider right away if you have any mental changes that are new, worse, or worry you.

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.**
- **Tell your healthcare provider if you are taking medicines to treat diabetes including an insulin or sulfonylurea which could increase your risk of low blood sugar. Talk to your healthcare provider about low blood sugar levels and how to manage them.**

- **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 kidneys, 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. It is not known if Zepbound passes 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 will be 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 contact Lilly at 1-800-LillyRx (1-800-545-5979).

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.
- Zepbound is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm.
- **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, seek medical advice promptly, or contact a Poison Center expert right away at 1-800-222-1222.

Zepbound injection is approved as a 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg per 0.5 mL in single-dose pen or single-dose vial.

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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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 nearly 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

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), including statements about the efficacy and safety of Mounjaro (tirzepatide) as a potential treatment for children and adolescents with type 2 diabetes, and reflects Lilly's current belief 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 can be no guarantee that future study results will be consistent with the 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, 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.

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Refer to: Brooke Frost; brooke.frost@lilly.com; 317-432-9145 (Media)
Michael Czapar; czapar_michael_c@lilly.com; 317-617-0983 (Investors)

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