Lilly's tirzepatide reduced obstructive sleep apnea (OSA) severity, with up to 51.5% of participants meeting the criteria for disease resolution

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In the primary endpoint, tirzepatide reduced moderate-to-severe OSA severity by up to 62.8% (about 30 fewer events per hour)

In a key secondary endpoint from two clinical studies, 43.0% and 51.5% of participants taking tirzepatide at the highest dose reached the criteria for disease resolution as defined by apnea-hypopnea index and Epworth Sleepiness Scale measures

Lilly submitted tirzepatide for the treatment of moderate-to-severe OSA and obesity to the U.S. Food and Drug Administration (FDA) and will initiate submissions for other global regulatory agencies in the coming weeks

INDIANAPOLIS, June 21, 2024 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced detailed results from the SURMOUNT-OSA phase 3 clinical trials evaluating tirzepatide injection (10 mg or 15 mg) for the treatment of moderate-to-severe obstructive sleep apnea (OSA) in adults with obesity, with and without positive airway pressure (PAP) therapy. In both studies, tirzepatide achieved all primary and key secondary endpoints for both the efficacy[i] and treatment-regimen[ii] estimands and demonstrated a mean reduction of up to 62.8% on the apnea-hypopnea index (AHI), or about 30 fewer events restricting or blocking a person's airflow per hour of sleep, compared to placebo. Full results were published in *The New England Journal of Medicine (NEJM)* and presented at the American Diabetes Association® (ADA) 84th Scientific Sessions.

In a key secondary endpoint, the efficacy estimand showed that 43.0% (Study 1) and 51.5% (Study 2) of participants treated with tirzepatide at the highest dose met the criteria for disease resolution. In this context, "disease resolution" means achieving an AHI of fewer than 5 events per hour, or an AHI of 5-14 events per hour and an Epworth Sleepiness Scale (ESS) score of ≤10. ESS is a standard questionnaire designed to assess excessive daytime sleepiness.[1-4]

OSA is a complex disease that can impact the progression of serious cardiometabolic complications, including hypertension, coronary heart disease, stroke, heart failure, atrial fibrillation and type 2 diabetes.[5] Participants treated with tirzepatide in both studies experienced significant improvements in all key secondary endpoints including systolic blood pressure, hypoxic burden and high-sensitivity C-reactive protein (hsCRP), an inflammation marker, compared to placebo.

"In the trials, patients with moderate-to-severe obstructive sleep apnea and obesity treated with tirzepatide experienced about 30 fewer disruptive events every hour of sleep and nearly half achieved disease resolution," said Atul Malhotra, MD, Peter C. Farrell presidential chair, professor of medicine at University of California San Diego School of Medicine and director of sleep medicine at UC San Diego Health. "OSA can be very disruptive to daily life and affects a person's long-term health when left untreated because it can lead to serious cardiometabolic complications. These data support the efficacy of tirzepatide in adults living with moderate-to-severe OSA and obesity and has the potential to add to our toolbox for OSA treatment."

Full Results:

SURMOUNT-OSA Study 1 – Participants Not on PAP Therapy		
	Efficacy Estimand Results at 52 Weeks	**Treatment-Regimen Estimand Results at 52 Weeks**
Primary Endpoint – Change in AHI from Baseline		
Tirzepatide*	-27.4	-25.3
Placebo	-4.8	-5.3
Secondary Endpoint – Percent Change in AHI from Baseline		
Tirzepatide*	-55.0 %	-50.7 %
Placebo	-5.0 %	-3.0 %
Secondary Endpoint – Percentage of Participants with AHI <5 or AHI 5-14 with ESS ≤10		
Tirzepatide*	43.0 %	42.2 %
Placebo	14.9 %	15.9 %
Secondary Endpoint – Percentage of Participants with ≥50% AHI Reduction		
Tirzepatide*	62.3 %	61.2 %
Placebo	19.2 %	19.0 %
Secondary Endpoint – Percent Change in Body Weight		
Tirzepatide*	-18.1 %	-17.7 %
Placebo	-1.3 %	-1.6 %

SURMOUNT-OSA Study 2 – Participants Used PAP Therapy

	Efficacy Estimand Results at 52 Weeks	Treatment-Regimen Estimand Results at 52 Weeks
Primary Endpoint – Change in AHI from Baseline		
Tirzepatide*	-30.4	-29.3
Placebo	-6.0	-5.5
Secondary Endpoint – Percent Change in AHI from Baseline		
Tirzepatide*	-62.8 %	-58.7 %
Placebo	-6.4 %	-2.5 %
Secondary Endpoint – Percentage of Participants with AHI <5 or AHI 5-14 with ESS ≤10		
Tirzepatide*	51.5 %	50.2 %
Placebo	13.6 %	14.3 %
Secondary Endpoint – Percentage of Participants with ≥50% AHI Reduction		
Tirzepatide*	74.3 %	72.4 %
Placebo	22.9 %	23.3 %
Secondary Endpoint – Percent Change in Body Weight		
Tirzepatide*	-20.1 %	-19.6 %
Placebo	-2.3 %	-2.3 %

**For both SURMOUNT-OSA Study 1 and Study 2, tirzepatide MTD is maximum tolerated dose of 10 mg or 15 mg once-weekly. The starting dose of 2.5 mg tirzepatide was increased by 2.5 mg every four weeks until maximum tolerated dose was achieved. Participants who tolerated 15 mg continued on 15 mg as their maximum tolerated dose. Participants who tolerated 10 mg but did not tolerate 15 mg continued on 10 mg as their maximum tolerated dose.*

"There are currently no pharmaceutical treatment options to address the underlying cause of OSA, a complex disease that disrupts the daily lives of 80 million people in the U.S. alone and is linked to serious health complications," said Jeff Emmick, MD, Ph.D., senior vice president, product development, Lilly. "The SURMOUNT-OSA results showed a significant proportion of patients with moderate-to-severe OSA and obesity treated with tirzepatide achieved disease resolution based on predetermined AHI and ESS measures, at which point PAP therapy may not be recommended." [4-9]

The overall safety profile of tirzepatide in SURMOUNT-OSA studies was similar to previously reported SURMOUNT and SURPASS trials. The most commonly reported adverse events in SURMOUNT-OSA were gastrointestinal related and generally mild to moderate in severity. The most frequent events reported by those on tirzepatide compared with placebo, respectively, were diarrhea (26.3% vs 12.5%), nausea (25.4% vs 10.0%) and vomiting (17.5% vs 4.2%) in SURMOUNT-OSA Study 1, and diarrhea (21.8% vs 8.8%), nausea (21.8% vs 5.3%) and constipation (15.1% vs 4.4%) in SURMOUNT-OSA Study 2. Adverse events led to discontinuation of study treatment in 9 participants taking tirzepatide (5 in Study 1 and 4 in Study 2) and 10 taking placebo (2 in Study 1 and 8 in Study 2).

Tirzepatide is the only approved GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1) treatment for chronic weight management, commercialized as Zepbound® in the U.S. and Mounjaro® in some global markets outside the U.S. Lilly submitted tirzepatide for the treatment of moderate-to-severe OSA and obesity to the U.S. Food and Drug Administration (FDA) with regulatory action anticipated as early as the end of this year. Lilly received FDA Fast Track designation for moderate-to-severe OSA in patients with obesity.

About SURMOUNT-OSA

SURMOUNT-OSA (NCT05412004) was a multi-center, randomized, double-blind, parallel, placebo-master protocol comparing the efficacy and safety of tirzepatide to placebo in adults living with moderate-to-severe obstructive sleep apnea and obesity who were unable or unwilling to use positive airway pressure (PAP) therapy (Study 1) and those who were and planned to stay on PAP therapy during the duration of the trial (Study 2). Under a master protocol, the trials randomized 469 participants across the U.S., Australia, Brazil, China, Czechia, Germany, Japan, Mexico and Taiwan in a 1:1 ratio to receive tirzepatide maximum tolerated dose (MTD) 10 mg or 15 mg or placebo. The primary objective of both studies was to demonstrate that tirzepatide is superior in change in apnea-hypopnea index (AHI) from baseline at 52 weeks as compared to placebo.

SURMOUNT-OSA utilized a MTD of 10 mg or 15 mg once-weekly. The starting dose of 2.5 mg tirzepatide was increased by 2.5 mg every four weeks until maximum tolerated dose was achieved. Participants who tolerated 15 mg continued on 15 mg as their MTD. Participants who tolerated 10 mg but did not tolerate 15 mg continued on 10 mg as their MTD.

INDICATION AND SAFETY SUMMARY WITH WARNINGS

Zepbound® (ZEHP-bownd) is an injectable prescription medicine that may help adults with obesity, or with excess weight (overweight) who also have weight-related medical problems, lose weight and keep it off. 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 when taken with other prescription, over-the-counter, or herbal weight loss products. It is not known if Zepbound can be used in people who have had pancreatitis. It is not known if Zepbound is safe and effective for use in children under 18 years of age.

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.

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 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 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 insulin or sulfonylureas 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?
❑ 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.

How to take

- Read the **Instructions for Use** that come with Zepbound.
- Use Zepbound exactly as your healthcare provider says.
- 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 18002221222.

Learn more
Zepbound is a prescription medicine. For more information, 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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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 can be used in people who have had inflammation of the pancreas (pancreatitis). Mounjaro is not for use in people with type 1 diabetes. It is not known if Mounjaro is safe and effective for use in children under 18 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 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.

Kidney problems (kidney failure). In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems to get worse. 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.

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 kidneys, 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 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.
- Mounjaro is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm.
- **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 seek medical advice promptly.

Learn more
Mounjaro is a prescription medicine. For more information, call 1-833-807-MJRO (833-807-6576) or go to **www.mounjaro.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 nearly 150 years, and today our medicines help more than 51 million 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

[i] The efficacy estimand represents efficacy prior to discontinuation of study drug.

[ii] The treatment-regimen estimand represents the estimated average treatment effect regardless of treatment discontinuation.

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 tirzepatide as a potential option for adults with moderate-to-severe obstructive sleep apnea and 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 tirzepatide will prove to be a safe and effective treatment for moderate-to-severe sleep apnea, that tirzepatide 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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