Lilly receives U.S. FDA Fast Track designation for tirzepatide for the treatment of adults with obesity, or overweight with weight-related comorbidities

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The Fast Track designation accelerates tirzepatide's path to U.S. FDA submission for the treatment of adults with obesity, or overweight with weight-related comorbidities

INDIANAPOLIS, Oct. 6, 2022 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the investigation of tirzepatide for the treatment of adults with obesity, or overweight with weight-related comorbidities. The FDA grants Fast Track designation to facilitate the development and expedite the review of medicines to treat serious conditions and fill an unmet medical need. Fast Track designation is intended to bring promising medicines to patients sooner.

Based on discussions with the FDA, Lilly plans to initiate a rolling submission of a new drug application (NDA) for tirzepatide in adults with obesity or overweight this year, which when complete, will be based primarily on results from two Phase 3 clinical trials: SURMOUNT-1, which is complete, and SURMOUNT-2, which is expected to complete by the end of April 2023. The rolling submission allows Lilly to submit completed sections of an application for review by FDA, rather than wait until all sections are completed.

Assuming positive SURMOUNT-2 results, Lilly aims to complete the submission shortly after SURMOUNT-2 data is available. The Fast Track designation, along with a rolling submission, accelerates tirzepatide's path to FDA submission.

"We are pleased with the FDA's decision to grant Fast Track designation for tirzepatide, and we look forward to completing our rolling submission next year," said Mike Mason, president, Lilly Diabetes. "Obesity is a chronic disease that impacts the health of nearly 100 million Americans and is a significant driver of healthcare costs. While diet and exercise are important steps, most patients don't achieve their desired treatment goals with only diet and exercise. We are dedicated to helping people living with obesity through our research and development of innovative treatments like tirzepatide, which produced significant weight reductions in patients taking tirzepatide for type 2 diabetes in SURPASS. Tirzepatide also helped nearly two-thirds of participants on the highest dose reduce their body weight by at least 20 percent in SURMOUNT-1."

About SURMOUNT-1, SURMOUNT-2 and the SURMOUNT clinical trial program[1,2]
SURMOUNT-1 (NCT04184622) is a multi-center, randomized, double-blind, parallel, placebo-controlled trial, which compared the efficacy and safety of tirzepatide 5 mg, 10 mg and 15 mg to placebo as an adjunct to a reduced-calorie diet and increased physical activity in adults without type 2 diabetes who have obesity, or overweight with at least one of the following comorbidities: hypertension, dyslipidemia, obstructive sleep apnea or cardiovascular disease. The trial randomized 2,539 participants across the U.S., Argentina, Brazil, China, India, Japan, Mexico, Russia and Taiwan in a 1:1:1:1 ratio to receive either tirzepatide 5 mg, 10 mg or 15 mg or placebo. The co-primary objectives of the study were to demonstrate that tirzepatide 10 mg and/or 15 mg was superior in percentage of body weight reductions from baseline and percentage of participants achieving ≥5% body weight reduction at 72 weeks compared to placebo. Participants who had pre-diabetes at study commencement will remain enrolled in SURMOUNT-1 for an additional 104 weeks of treatment following the initial 72-week completion date to evaluate the impact on body weight and potential differences in progression to type 2 diabetes at three years of treatment with tirzepatide compared to placebo.

All participants in the tirzepatide treatment arms started the study at a dose of tirzepatide 2.5 mg once-weekly and then increased the dose in a step-wise approach at four-week intervals to their final randomized maintenance dose of 5 mg (via a 2.5 mg step), 10 mg (via steps at 2.5 mg, 5 mg and 7.5 mg) or 15 mg (via steps at 2.5 mg, 5 mg, 7.5 mg, 10 mg and 12.5 mg).

SURMOUNT-2 (NCT04657003) is a multi-center, randomized, double-blind, parallel, placebo-controlled trial comparing the efficacy and safety of tirzepatide 10 mg and 15 mg to placebo as an adjunct to a reduced-calorie diet and increased physical activity in adults with type 2 diabetes who have obesity or overweight. The trial randomized 938 participants across the U.S., Argentina, Brazil, India, Japan, Puerto Rico, Russia and Taiwan in a 1:1:1 ratio to receive either tirzepatide 10 mg or 15 mg or placebo. The co-primary objectives of the study are to demonstrate that tirzepatide 10 mg and/or 15 mg is superior in percentage of body weight change from baseline and percentage of participants achieving ≥5% body weight reduction at 72 weeks compared to placebo.

The SURMOUNT Phase 3 global clinical development program for tirzepatide began in late 2019 and has enrolled more than 5,000 people with obesity or overweight across six clinical trials, four of which are global studies. Results from SURMOUNT-2, -3 and -4 are anticipated in 2023.

About tirzepatide
Tirzepatide is a once-weekly GIP (glucose-dependent insulinotropic polypeptide) receptor and GLP-1 (glucagon-like peptide-1) receptor agonist. Tirzepatide is a single novel molecule that activates the body's receptors for GIP and GLP-1, which are natural incretin hormones. GIP is a hormone that may complement the effects of GLP-1 receptor agonism. GIP has been shown to decrease food intake while blunting the metabolic adaptive responses that usually occur with calorie restriction resulting in weight reductions, and when combined with GLP-1 receptor agonism, may result in greater effects on markers of metabolic dysregulation such as body weight, glucose and lipids. Tirzepatide is in Phase 3 development for adults with obesity, or overweight with weight-related comorbidity. It is also being studied as a potential treatment for heart failure with preserved ejection fraction (HFpEF), obstructive sleep apnea (OSA), and non-alcoholic steatohepatitis (NASH). Studies of tirzepatide in chronic kidney disease and in morbidity/mortality in obesity are planned as well.

Tirzepatide was approved as Mounjaro® (tirzepatide) by the FDA on May 13, 2022. Mounjaro is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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 unites caring with discovery to create medicines that 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 47 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/newsroom or follow us on Facebook, Instagram, Twitter and LinkedIn. P-LLY

Lilly 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 treatment for adults with obesity or overweight and the timeline for regulatory submissions and actions, future readouts, presentations and other milestones relating to tirzepatide 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 research development and commercialization. Among other things, there can be no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with the results to date, that tirzepatide will receive additional regulatory approvals, or that tirzepatide will be commercially successful. 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.

References

1. Jastreboff, A., Arrone, J., Ahmad, N. et al. Tirzepatide Once Weekly for the Treatment of Obesity. N Engl J Med 2022; 387:205-216 DOI: 10.1056/NEJMoa2206038
2. le Roux, C. Zhang, S., Aronne, L. et. al. Tirzepatide for the Treatment of Obesity: Rationale and Design of the SURMOUNT Clinical Development Program 2022 Obesity doi: 10.1002/oby.23612

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