Lilly to present new research in the treatment of diabetes and obesity at the American Diabetes Association's® 83rd Scientific Sessions

June 20, 2023

Full SURMOUNT-2 phase 3 data on the efficacy and safety of tirzepatide for chronic weight management in adults with obesity or overweight and type 2 diabetes

New phase 2 data for retatrutide and orforglipron showcase promise of Lilly's pipeline and commitment to transform diabetes and obesity care

INDIANAPOLIS, June 20, 2023 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will present 40 abstracts across its diabetes and obesity portfolio and pipeline at the American Diabetes Association's® (ADA) 83rd Scientific Sessions in San Diego from June 23 - 26. Lilly will also share data on three investigational medicines for the treatment of obesity or overweight during two ADA-sponsored symposiums and one oral presentation.

"Our data presented at the ADA demonstrate continued efforts to deliver better outcomes for the millions of people living with diabetes, obesity and other chronic diseases," said Jeff Emmick, MD, Ph.D., senior vice president, product development, Lilly. "Our incretin portfolio, the most expansive in the industry, has the potential to transform treatment for chronic diseases."

Key ADA Data Presentations

- **SURMOUNT-2:** The full results of the phase 3 clinical trial evaluating the efficacy and safety of tirzepatide for chronic weight management in adults with obesity or overweight and type 2 diabetes, will be presented in an ADA-sponsored symposium. This presentation follows the topline data that Lilly announced on April 27, which showed that tirzepatide led to superior weight reductions versus placebo for all doses. The symposium titled *SURMOUNT-2 Trial Results and Potential Role of Tirzepatide in Treating Obesity in Type 2 Diabetes* is scheduled on Friday, June 23, from 3:45-5:15 PM PDT and will be livestreamed for virtually registered attendees.
- **Orforglipron:** An oral presentation on Lilly's phase 2 trial results will highlight the potential for orforglipron, a daily oral GLP-1, in adults with obesity or overweight with at least one weight-related comorbidity, compared to placebo. The oral presentation, *Effect of Oral Nonpeptide GLP-1 Receptor Agonist Orforglipron (LY3502970) in Participants with Obesity or Overweight—A Phase 2 Study* is scheduled on Friday, June 23, from 2:15-2:30 PM PDT and will be livestreamed for virtually registered attendees. Lilly will also share phase 2 results of orforglipron in adults with type 2 diabetes in a poster presentation on Sunday, June 25 from 11:30 AM-12:30 PM PDT.
- **Retatrutide:** The full results of two phase 2 studies evaluating retatrutide, Lilly's GIP/GLP-1/Glucagon Receptor Triagonist, compared to placebo will be presented in an ADA-sponsored symposium. This presentation will discuss the efficacy and safety of retatrutide in adults with obesity or overweight with at least one weight-related comorbidity, as well as in people with type 2 diabetes. The symposium titled, *Retatrutide (LY3437943), a Novel GIP/GLP-1/Glucagon Receptor Triagonist —Obesity, NAFLD, and T2D Phase 2 Trial Results* is scheduled on Monday, June 26, from 1:30-3:00 PM PDT and will be livestreamed for virtually registered attendees.

Key ADA Data Abstracts

Abstract Number and Title	Presentation Details
Tirzepatide	
SURMOUNT-2 Symposium: SURMOUNT-2 Trial Results and Potential Role of Tirzepatide in Treating Obesity in Type 2 Diabetes (Includes Livestream)	Symposium; Friday, June 23; 3:45 PM-5:15 PM PDT
750-P: SURPASS(ing) an Era of Basal-Bolus Insulin Therapy: Tirzepatide vs Insulin Lispro TID Added-on to Poorly Controlled Basal Insulin–Treated Type 2 Diabetes (SURPASS-6)	Poster presentation; Sunday, June 25; 11:30 AM-12:30 PM PDT
Orforglipron	
52-OR: Effect of Oral Nonpeptide GLP-1 Receptor Agonist Orforglipron (LY3502970) in Participants with Obesity or Overweight—A Phase 2 Study	Oral presentation; Friday, June 23; 2:15 PM-2:30 PM PDT
761-P: Effect of Orforglipron vs. Placebo and Dulaglutide on Glycemic Control and Body Weight in Patients with Type 2 Diabetes	Poster presentation; Sunday, June 25; 11:30 AM-12:30 PM PDT
Retatrutide	

Retatrutide Symposium: Retatrutide (LY3437943), a Novel GIP/GLP-1/Glucagon Receptor Tri-Agonist—Obesity, NAFLD and T2D Phase 2 Trial Results (Includes Livestream)	Symposium; Monday, June 26; 1:30 PM-3:00 PM PDT

The full list of abstracts at the ADA's 83rd Scientific Sessions is available here.

About orforglipron
Orforglipron is an investigational nonpeptide oral glucagon-like peptide-1 (GLP-1) receptor agonist being studied for chronic weight management in people with obesity or overweight, as well as for glucose lowering in people with type 2 diabetes.

Orforglipron was discovered by Chugai Pharmaceutical Co., Ltd. and licensed by Lilly in 2018. Chugai and Lilly published the preclinical pharmacology data of this molecule together (PNAS 2020).

About retatrutide
Retatrutide is an investigational single molecule that activates the body's receptors for three hormones – glucagon, glucose-dependent insulinotropic polypeptide (GIP), and glucagon-like peptide-1 (GLP-1), and is being studied for the treatment of obesity. Retatrutide is an acylated peptide suitable for weekly injection. Preclinical and phase 1 data have been published (Cell Metab 2022; Lancet 2022).

About tirzepatide
Tirzepatide is a once-weekly GIP receptor and GLP-1 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 has been shown to decrease food intake and modulate fat utilization. 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 people with obesity and/or overweight with heart failure with preserved ejection fraction (HFpEF), obstructive sleep apnea (OSA), and non-alcoholic steatohepatitis (NASH). Studies of tirzepatide in chronic kidney disease (CKD) and in morbidity/mortality in obesity (MMO) are also ongoing.

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.

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 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/newsroom or follow us on Facebook, Instagram, Twitter and LinkedIn. P-LLY

MOUNJARO (tirzepatide) 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.

TR CON CBS 14SEP2022

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, orforglipron and retatrutide as potential treatments for adults with obesity or overweight and other diseases and the timeline for future readouts, presentations, and other milestones relating to tirzepatide, orforglipron and retatrutide and their 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 study results to date, that tirzepatide, orforglipron and retatrutide will prove to be safe and effective treatments for adults with obesity or overweight or other diseases, that tirzepatide will receive additional regulatory approvals orforglipron and retatrutide will receive 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.

Refer to: Courtney Kasinger; ckasinger@lilly.com, 317-501-7056 (Media)
Jessica Thompson; thompson_jessica@lilly.com, 317-499-2042 (Media)
Joe Fletcher; jfletcher@lilly.com, 317-296-2884 (Investors)

View original content to download multimedia:https://www.prnewswire.com/news-releases/lilly-to-present-new-research-in-the-treatment-of-diabetes-and-obesity-at-the-american-diabetes-associations-83rd-scientific-sessions-301855729.html

SOURCE Eli Lilly and Company