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FDA Approves Tirzepatide, A Potential Blockbuster Drug for Type 2 Diabetes

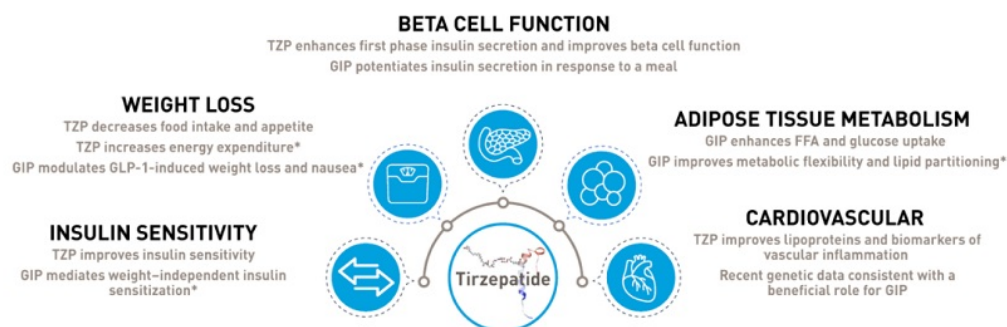
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On May 13, 2022, the U.S. FDA has approved Mounjaro (tirzepatide), developed by Eli Lilly and Company, for use in adults with type 2 diabetes in combination with controlled diet and exercise. Mounjaro is a glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptor dual agonist. It represents the first new class of diabetes medicines introduced in nearly a decade, according to a press release from Eli Lilly.

Type 2 diabetes is the most common form of diabetes in which the body makes or uses insulin in an abnormal way, resulting in higher blood glucose levels. Although there are [several medications available to treat diabetes](#), many patients still fail to reach the recommended blood glucose goals.

GIP and GLP-1 are the hormones that regulate blood sugar. Mounjaro is a first-in-class drug that activates both GIP and GLP-1 receptors, improving blood sugar control through a dual mechanism of action. Mounjaro is administered by weekly subcutaneous injections, and the dose can be adjusted according to tolerability. This therapy is one of Eli Lilly's key development programs. It has also been named by Evaluate as one of the [most anticipated drugs to be approved in 2022](#).

INSIGHT INTO TIRZEPATIDE'S MECHANISM OF ACTION AMBITIOUS PROGRAM OF PRECLINICAL AND CLINICAL STUDIES TO UNDERSTAND MOA



Note: References included in Appendix; * shown in preclinical models; MoA = Mechanism of Action; TZP = Tirzepatide; GIP = Glucose-dependent Insulinotropic Polypeptide; FFA = Free Fatty Acids
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11

▲ Mechanism of action of Tirzepatide (source: Lilly website)

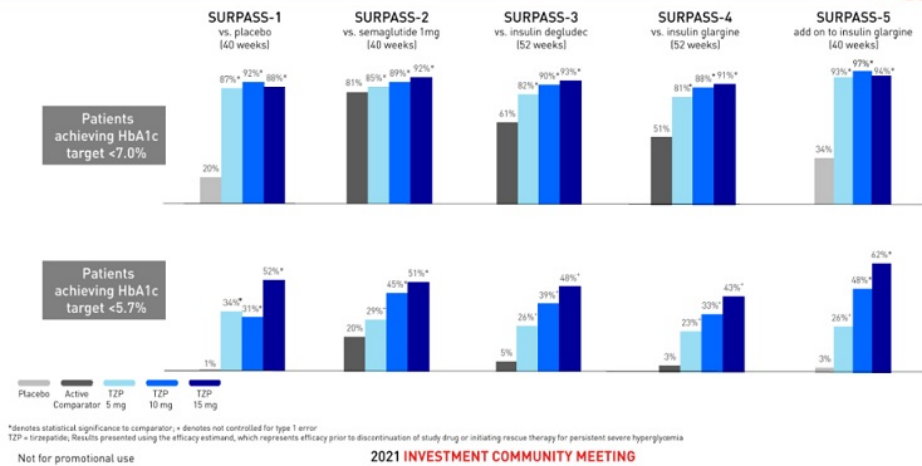
Different doses of Mounjaro were evaluated in five clinical trials as a stand-alone therapy or in combination with other diabetes medications. Patients receiving the maximum recommended dose of Mounjaro (15 mg) as monotherapy had an average 1.6% reduction in hemoglobin A1c (HbA1c, a measure of blood sugar control) compared to placebo. In combination with long-acting insulin, Mounjaro reduced HbA1c levels by 1.5% compared to placebo. Mounjaro also lowered HbA1c levels even more in clinical trials comparing it to other diabetes therapies.

Eli Lilly & Co.
Exhibit 2034
EMPOWER v. Eli Lilly
IPR2025-01024
Ex. 2034-001

TIRZEPATIDE T2D SURPASSED EXPECTATIONS

HELPED UP TO 97% AND 62% OF PATIENTS REACH HbA1c BELOW 7.0% AND 5.7%, RESPECTIVELY

Lilly



2021 INVESTMENT COMMUNITY MEETING

14

▲ Mounjaro significantly reduced HbA1c levels in 5 clinical trials (source: Lilly website)

Obesity was common among clinical trial participants, with most participants having a BMI between 32 and 34 at enrollment. Among patients treated with the maximum recommended dose, those receiving Mounjaro monotherapy had an average weight loss of 15 pounds compared to placebo. In combination with insulin, Mounjaro resulted in an average weight loss of 23 pounds compared to placebo.

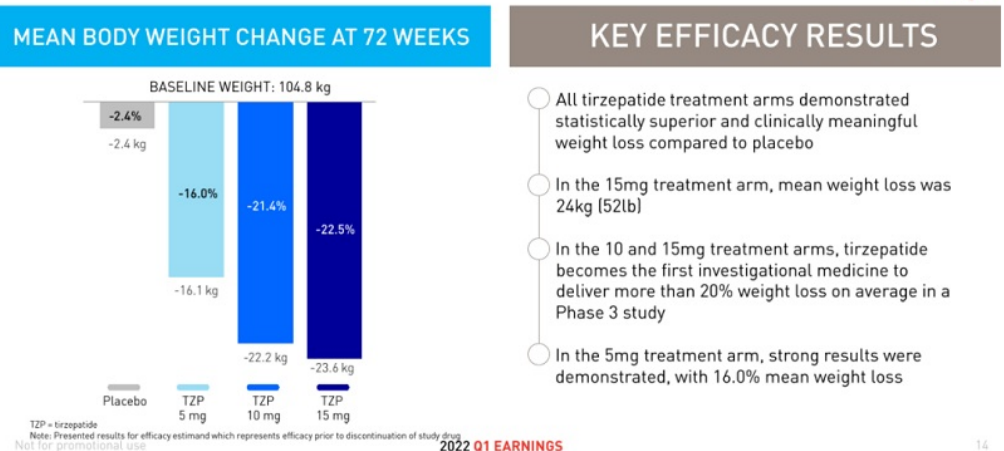
Mounjaro may cause nausea, vomiting, diarrhea, decreased appetite, constipation, abdominal pain, and upper abdominal discomfort.

In addition to helping patients with type 2 diabetes control their blood sugar, tirzepatide recently received positive results in a Phase 3 clinical trial for the treatment of generally obese individuals who do not have type 2 diabetes. The subgroup treated with the maximum dose of tirzepatide lost an average of 22.5% of their body weight (approximately 24 kg) and 63% of subjects lost at least 20% of their body weight! Lilly's press release notes that this is the first investigational drug to reduce body weight by more than 20% on average in a Phase 3 clinical trial.

SURMOUNT-1: EFFICACY

PARTICIPANTS ON HIGHEST DOSE ACHIEVED 22.5% WEIGHT LOSS ON AVERAGE

Lilly



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14

▲ Tirzepatide significantly reduces body weight in obese individuals (source: Lilly website)

Eli Lilly is currently testing the effectiveness of tirzepatide for treating different types of obese groups in a number of other



Top

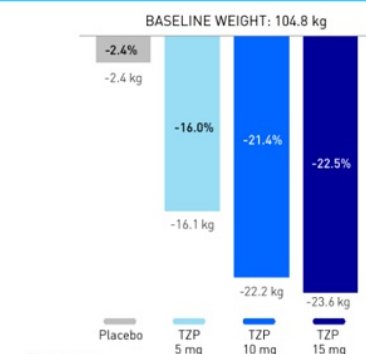
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SURMOUNT-1: EFFICACY

PARTICIPANTS ON HIGHEST DOSE ACHIEVED 22.5% WEIGHT LOSS ON AVERAGE

Lilly

MEAN BODY WEIGHT CHANGE AT 72 WEEKS



KEY EFFICACY RESULTS

- All tirzepatide treatment arms demonstrated statistically superior and clinically meaningful weight loss compared to placebo
- In the 15mg treatment arm, mean weight loss was 24kg (52lb)
- In the 10 and 15mg treatment arms, tirzepatide becomes the first investigational medicine to deliver more than 20% weight loss on average in a Phase 3 study
- In the 5mg treatment arm, strong results were demonstrated, with 16.0% mean weight loss

▲ Tirzepatide significantly reduces body weight in obese individuals (source: Lilly website)

Eli Lilly is currently testing the effectiveness of tirzepatide for treating different types of obese groups in a number of other Phase 3 clinical trials, which are expected to yield results next year. Eli Lilly said that obesity increases the risk of diabetes and many metabolic diseases, so treating obesity can improve people's health by reducing the chance of developing metabolic diseases and related complications.

References:

- [1] FDA Approves Novel, Dual-Targeted Treatment for Type 2 Diabetes. Retrieved May 13, 2022, from https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes?utm_medium=email&utm_source=govdelivery
- [2] FDA approves Lilly's Mounjaro™ (tirzepatide) injection, the first and only GIP and GLP-1 receptor agonist for the treatment of adults with type 2 diabetes. Retrieved May 13, 2022, from <https://www.prnewswire.com/news-releases/fda-approves-lillys-mounjaro-tirzepatide-injection-the-first-and-only-gip-and-glp-1-receptor-agonist-for-the-treatment-of-adults-with-type-2-diabetes-301547339.html>

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Top