

Category

Best Pharmaceutical Product

Drug / Device Name

Mounjaro® (tirzepatide) Injection

Compound/ Tech Name

Tirzepatide

Trade Name

Mounjaro®

Date of Approval

2022-05-13

Indications

Mounjaro is an FDA-approved treatment for adults with type 2 diabetes to improve glycemic control used along with diet and exercise.

Therapeutic Categories

Diabetes, Endocrinology, Chronic Disease

Background information and need for drug/device

Type 2 diabetes is a chronic, progressive condition that impacts 537 million adults worldwide. At current rates, total diagnoses are expected to reach 783 million by 2045 (IDF Diabetes Atlas 2021). In the U.S. alone, 37 million people live with diabetes, and 90-95% of them have type 2 diabetes (CDC).

Of those living with type 2 diabetes, only 1 in 2 people are reaching their target blood sugar goals (The New England Journal of Medicine), which underscores the complex nature of managing this disease. As a result, life expectancy is six years shorter for people living with type 2 diabetes than people without it (CDC).

These staggering outcomes demonstrate the need for continued research and new advances for pharmacological interventions that can help those living with type 2 diabetes reduce their risk of complications and live longer lives (CDC).

Links:

1. https://diabetesatlas.org/idfawp/resource-files/2021/07/IDF_Atlas_10th_Edition_2021.pdf
2. <https://www.cdc.gov/diabetes/basics/type2.html>
3. <https://pubmed.ncbi.nlm.nih.gov/34107181/>
4. <https://www.cdc.gov/diabetes/resources-publications/research-summaries/reaching-treatment-goals.html>

History of the development of the drug/device

Mounjaro was approved by the U.S. Food and Drug Administration (FDA) on May 13, 2022, for adults with type 2 diabetes to improve glycemic control used along with diet and exercise.

Mounjaro's FDA approval was based on data from the phase 3 SURPASS clinical trial program which included placebo and active comparators such as: injectable semaglutide 1 mg, titrated insulin glargine and titrated insulin degludec. Efficacy and safety were evaluated for Mounjaro 5 mg, 10 mg and 15 mg used alone or in combination with commonly prescribed diabetes medications, including metformin, SGLT2 inhibitors, sulfonylureas and insulin glargine. Participants in the SURPASS program achieved average A1C reductions between 1.8% and 2.1% for Mounjaro 5 mg and between 1.7% and 2.4% for both Mounjaro 10 mg and Mounjaro 15 mg. While not currently indicated for weight loss, mean change in body weight was a key secondary endpoint in all SURPASS studies. Participants treated with Mounjaro lost between 12 lbs. (5 mg) and 25 lbs. (15 mg) on average.

The SURPASS phase 3 global clinical development program for tirzepatide began in late 2018 and included five global registration trials and additional studies conducted for regulatory submissions in Japan and China. The duration of the studies ranged from 40 to 52 weeks and evaluated the efficacy and safety of Mounjaro 5 mg, 10 mg and 15 mg as an adjunct to diet and exercise as monotherapy, add-on to 1 to 3 orals and add-on to basal insulin.

Adverse events reported in at least 5% of patients treated with Mounjaro include nausea, diarrhea, decreased appetite, vomiting, constipation, indigestion (dyspepsia), and stomach (abdominal) pain. The labeling for Mounjaro contains a Boxed Warning regarding thyroid C-cell tumors. Mounjaro is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2.

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition

Mounjaro is the first and only approved treatment in a different class of medication for type 2 diabetes. It works differently than other type 2 diabetes medications by directly activating GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1) pathways to help regulate blood sugar.

Half of the 37 million Americans with type 2 diabetes are not reaching their target blood sugar goals. Due to this, Lilly has developed an alternative solution combining actions of GIP and GLP-1 in one molecule; while GLP-1 receptor agonists have been well established in therapy for type 2 diabetes, GIP has not been developed as a therapeutic option. Lilly utilized its scientific and medical expertise to research a completely new class of medicine, which unveiled Mounjaro as a new treatment option that could solve these unmet needs. In clinical trials, Mounjaro showed efficacy that is significantly greater than what has been observed with GLP-1 receptor agonists: up to 97% of patients achieved their treatment goal for glucose lowering and up to 43% of patients achieved >15% weight loss. By activating both the GIP and GLP-1 receptors, Mounjaro improves insulin secretion beyond what can be achieved with a single GLP-1 receptor agonist; in addition, insulin sensitivity is improved in both a weight-independent and weight-dependent manner, potentially due to the action of GIP on adipose tissue. The U.S. FDA approval of Mounjaro represented the first new class of diabetes medicines introduced in nearly a decade and demonstrated a new approach to manage type 2 diabetes.

Please provide appropriate references (ie Pubmed links)

Mounjaro FDA approval release: <https://investor.lilly.com/news-releases/news-release-details/fda-approves-lillys-mounjaro-tm-tirzepatide-injection-first-and>

SURPASS clinical trial program releases:

1. SURPASS-1: <https://investor.lilly.com/news-releases/news-release-details/lillys-surpass-1-results-published-lancet-show-tirzepatides>
2. SURPASS-2: <https://investor.lilly.com/news-releases/news-release-details/lillys-surpass-2-results-published-new-england-journal-medicine>
3. SURPASS-3 & 5: <https://investor.lilly.com/news-releases/news-release-details/tirzepatide-significantly-reduced-a1c-and-body-weight-people>
4. SURPASS-4: <https://investor.lilly.com/news-releases/news-release-details/tirzepatide-results-published-lancet-show-superior-a1c-and-body>

Other references:

1. IDF Diabetes Atlas (2021), 10th Edition. International Diabetes Federation. https://diabetesatlas.org/idfawp/resource-files/2021/07/IDF_Atlas_10th_Edition_2021.pdf
2. Type 2 Diabetes. Centers for Disease Control and Prevention. <https://www.cdc.gov/diabetes/basics/type2.html>
3. Trends in Diabetes Treatment and Control in U.S. Adults, 1999-2018. Michael Fang, et al. https://diabetesatlas.org/idfawp/resource-files/2021/07/IDF_Atlas_10th_Edition_2021.pdf
4. People With Diabetes Can Live Longer by Meeting Their Treatment Goals. Centers for Disease Control and Prevention. <https://www.cdc.gov/diabetes/resources-publications/research-summaries/reaching-treatment-goals.html>
5. Obesity and Overweight. World Health Organization. <https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight>