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FDA Approves Lilly's Mounjaro™ (tirzepatide)

In May 2022, the FDA approved Mounjaro (tirzepatide) a subcutaneous once-weekly glucose-dependent insulinotropic polypeptide (GIP) 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.

The phase 3 SURPASS clinical trial compared tirzepatide to injectable semaglutide 1mg, insulin glargine and insulin degludec over 40 to 52 weeks. The study allowed Mounjaro 5mg, 10mg, and 15mg to be used alone or in combination with other commonly prescribed medications including metformin, SGTL-2 inhibitors, sulfonylureas, and insulin glargine. The trial results found that Mounjaro 5mg achieved an average A1C reduction between 1.8% and 2.1% and between 1.7% and 2.4% for Mounjaro 10mg and 15mg. In comparison, Mounjaro at the maximum recommended doses had an A1C lowering of 0.5% more than semaglutide, 0.9% more than insulin degludec, and 1% more than insulin glargine. Although not indicated for weight loss, the secondary endpoint of the study found participants lost an average of 12lbs on the 5mg dose of Mounjaro and 25lbs with the 15mg dose. The average weight loss with the maximum recommended dose of Mounjaro was 12lbs more than semaglutide, 29lbs more than insulin degludec, and 27lbs more than insulin glargine.

Similar to the GLP-1 agonists, the most common side effects of Mounjaro included nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain. Mounjaro also has a boxed warning regarding thyroid C-cell tumors and this medication is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 or type 1 diabetes. Additionally, it is not known if Mounjaro can be used in patients with a history of pancreatitis.

Mounjaro is will be available in six doses (2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15mg). The pen-type is similar to that of Lilly's other product, Trulicity, in using an auto-injector pen with a pre-attached, hidden needle that patients do not handle or see. Dosing of Mounjaro requires a slow titration as follows: 2.5mg once weekly for 4 weeks THEN 5mg once weekly for 4 weeks. If additional glycemic control is needed it is recommended to titrate in increments of 2.5mg after at least 4 weeks at the current dose. The maximum dose is 15mg once weekly. It is expected in the upcoming weeks Mounjaro will be available in the United States.

The American Diabetes Association Standards of Medical Care in Diabetes were last updated in January 2022 and do not currently have a recommendation for use of Mounjaro.

References:

1. Commissioner, O. of the. (n.d.). FDA approves novel, dual-targeted treatment for type 2 diabetes. U.S. Food and Drug Administration. Retrieved May 24, 2022, from https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes
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. Eli Lilly and Company. (2022, May 13). Retrieved May 24, 2022, from https://investor.lilly.com/news-releases/news-release-details/fda-approves-lillys-mounjarotm-tirzepatide-injection-first-and