## Ozempic® (semaglutide) – New strength

- On March 28, 2022, Novo Nordisk announced the FDA approval of a 2 mg dose of Ozempic (semaglutide).
- Ozempic 2 mg is delivered via a single-patient-use pen. Ozempic was previously available as a single-patient-use pen that delivers 0.25 mg, 0.5 mg, or 1 mg per injection.
- Ozempic is approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM) and to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with T2DM and established cardiovascular disease.
- The efficacy of Ozempic 2 mg was established in a 40-week, double-blind study in 961 patients with T2DM currently treated with metformin with or without sulfonylurea treatment. Patients were randomized to Ozempic 1 mg or 2 mg once weekly.
    - The change in HbA1c at week 40 was 1.9% and 2.1% for Ozempic 1 mg and Ozempic 2 mg (difference of -0.2, 95% CI: -0.31, -0.04; $p < 0.01$).
- Ozempic carries a boxed warning for risk of thyroid C-cell tumors.
- Ozempic should be started with a 0.25 mg subcutaneous (SC) injection once weekly for 4 weeks. The 0.25 mg dosage is intended for treatment initiation and is not effective for glycemic control. After 4 weeks on the 0.25 mg dosage, the dosage should be increased to 0.5 mg once weekly.
    - If additional glycemic control is needed after at least 4 weeks on the 0.5 mg dosage, the dosage may be increased to 1 mg once weekly.
    - If additional glycemic control is needed after at least 4 weeks on the 1 mg dosage, the dosage may be increased to 2 mg once weekly. The maximum recommended dosage is 2 mg once weekly.
- Novo Nordisk plans to launch Ozempic 2 mg single-patient-use pens in the second quarter of 2022.