Ozempic® (semaglutide) – New indication

- On January 28, 2025, Novo Nordisk announced the FDA approval of Ozempic (semaglutide), **to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD)**.

- Ozempic is also approved:

    - As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
    - To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

- Ozempic is the first GLP-1 receptor agonist approved for T2DM and CKD.

- The approval of Ozempic for the new indication was based on FLOW, a randomized, double-blind, placebo-controlled, event driven trial in 3,533 adults with T2DM and CKD. All patients needed to receive standard of care background therapy, including a maximum tolerated labeled dose of a renin-angiotensin-aldosterone system (RAAS) blocking agent, unless such treatment was contraindicated or not tolerated. Patients were randomized to receive Ozempic or placebo and were followed for a median of 41 months. The primary compositive endpoint was the incidence of a sustained decline in eGFR of ≥ 50%, sustained eGFR < 15 mL/min/1.73 m^2, chronic renal replacement therapy, renal death, or cardiovascular death.

    - Ozempic significantly reduced the incidence of the primary composite endpoint by 24% (95% CI: 0.66, 0.88; p = 0.0003).
    - The treatment effect reflected a reduction in a sustained decline in eGFR of ≥ 50%, progression to kidney failure and cardiovascular death. There were few renal deaths during the trial.
    - Ozempic also reduced the annual rate of change in eGFR, the incidence of a composite cardiovascular endpoint, consisting of non-fatal myocardial infarction, non-fatal stroke, and cardiovascular death, and the incidence of all-cause death.

- Ozempic carries a boxed warning for the **risk of thyroid C-cell tumors**.

- The recommended initial dose of Ozempic is 0.25 mg **injected subcutaneously once weekly** for 4 weeks. After 4 weeks on the 0.25 mg dosage, the dosage can be increased to 0.5 mg once weekly. For patients with CKD, the dosage should be increased to the maintenance dosage of 1 mg once weekly, after at least 4 weeks on the 0.5 mg dosage.

    - Refer to the Ozempic drug label for dosing for its other indications.