## Jardiance® (empagliflozin) – New indication

- On September 22, 2023, Eli Lilly announced the FDA approval of Jardiance (empagliflozin), to reduce the risk of sustained decline in estimated glomerular filtration rate (eGFR), end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease (CKD) at risk of progression.
    - Jardiance is not recommended for the treatment of CKD in patients with polycystic kidney disease or patients requiring or with a recent history of intravenous immunosuppressive therapy or greater than 45 mg of prednisone or equivalent for kidney disease. Jardiance is not expected to be effective in these populations.
- Jardiance is the second sodium-glucose cotransporter 2 (SGLT2) inhibitor approved for a CKD indication. AstraZeneca's Farxiga® (dapagliflozin) is approved to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with CKD at risk of progression.
- Jardiance is also approved:
    - To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure
    - To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease
    - As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.
- The approval of Jardiance for the new indication was based on EMPA-KIDNEY, a randomized, double-blind, placebo-controlled study in 6,609 adults with CKD. Patients were randomized to Jardiance or placebo and were followed for a median of 24 months. The primary composite endpoint was time to a first event of either cardiovascular death or kidney disease progression, defined as end-stage kidney disease (the need for kidney replacement therapy such as dialysis or kidney transplantation), a sustained decline in eGFR to < 10 mL/min/1.73 $m^2$, kidney death or a sustained decline of ≥ 40% in eGFR from randomization.
    - Jardiance was superior to placebo in reducing the risk of the primary composite endpoint. The event rate was 13.1% for Jardiance vs. 16.9% for placebo (hazard ratio 0.72, 95% CI: 0.64, 0.82; p < 0.0001).
- The recommended dose of Jardiance for the treatment of CKD in adults is 10 mg orally once daily in the morning.
- Refer to the Jardiance drug label for dosing for all its other uses.