Farxiga® (dapagliflozin) – Expanded indication

- On May 9, 2023, AstraZeneca announced the FDA approval of Farxiga (dapagliflozin), to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure.
    - This approval expands the use of Farxiga for heart failure to include patients with preserved ejection fraction. Farxiga was previously approved for reduced ejection fraction patients.
- Farxiga is also approved:
    - To reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease (ESKD), cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.
    - To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors.
    - As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- The approval of Farxiga for the expanded indication was based on DELIVER, a randomized, double-blind, placebo-controlled, event-driven study in 6,263 heart failure patients with left ventricular ejection fraction (LVEF) greater than 40%, with or without type 2 diabetes. Patients were randomized to Farxiga or placebo and were followed for a median of 28 months. The primary composite endpoint was the time to first occurrence of cardiovascular death, hospitalization for heart failure or urgent heart failure visit.
    - The event rate (number of patients with event per 100 patient years of follow-up) for the composite primary endpoint was 7.8 with Farxiga vs. 9.6 with placebo (hazard ratio 0.82, 95% CI: 0.73, 0.92; p = 0.0008).
- The most common adverse reactions (≥ 5%) with Farxiga use were female genital mycotic infections, nasopharyngitis, and urinary tract infections.
- The recommended dose of Farxiga for all uses is based on eGFR:
    - eGFR 45 or greater: To improve glycemic control, the recommended starting dose is 5 mg orally once daily. The dose can be increased to 10 mg orally once daily for additional glycemic control. For all other indications, the recommended starting dose is 10 mg orally once daily.
    - eGFR 25 to less than 45: 10 mg orally once daily.
    - eGFR less than 25: Initiation is not recommended; however, patients may continue 10 mg orally once daily to reduce the risk of eGFR decline, ESKD, cardiovascular death and hospitalization for heart failure.