Jardiance® (empagliflozin) – New indication

- On August 18, 2021, Boehringer Ingelheim and Eli Lilly announced the FDA approval of Jardiance (empagliflozin), to reduce the risk of cardiovascular (CV) death plus hospitalization for heart failure (HHF) in adults with heart failure and reduced ejection fraction.

- Jardiance is also approved:

  - As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM)
  - To reduce the risk of CV death in adults with T2DM and established CV disease.

- The approval of Jardiance for the new indication was based on EMPEROR-Reduced, a randomized, double-blind, placebo-controlled study in 3,730 patients with chronic heart failure (New York Heart Association [NYHA] functional class II-IV) with reduced ejection fraction. Patients received Jardiance or placebo, as adjunct to standard of care heart failure therapy. The primary endpoint was the time to first event of either CV or HHF.

  - Jardiance significantly reduced the relative risk of the primary composite endpoint of time to CV death or HHF by 25% (5.3% absolute risk reduction, 0.75 hazard ratio, 95% CI: 0.65, 0.86; $p < 0.0001$) vs. placebo.
  - Additionally, Jardiance significantly reduced the risk of occurrence of HHF (first and recurrent).

- The recommended dose of Jardiance is 10 mg orally once daily in the morning.

  - For additional glycemic control, the dose may be increased to 25 mg in patients tolerating Jardiance.