FARXIGA is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (HFrEF) with or without type 2 diabetes (T2D). The landmark DAPA-HF trial is the largest SGLT2i trial to date, involving 4744 patients with HFrEF who were randomized 1:1 to FARXIGA 10 mg or placebo. The primary end point was a composite of cardiovascular death or hospitalization for heart failure.2

- FARXIGA reduced the risk of CV death or hospitalization for heart failure (HR, 0.74; 95% CI, 0.65-0.85)**
- The relative risk reduction for hospitalization for heart failure was 6%.

**The safety population included patients receiving ≥1 dose of trial medication: FARXIGA n=2368 and placebo n=2368.

### Important Safety Information for FARXIGA

**Warnings and Precautions**

- FARXIGA can cause intravascular volume depletion which may manifest as symptomatic hypotension. Before initiating FARXIGA in these patients, assess volume status and renal function.
- FARXIGA is not recommended for patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
- FARXIGA is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (HFrEF) with or without T2D.

### Adverse Reactions

- The most commonly reported adverse reactions associated with FARXIGA treatment in patients with HFrEF, with and without T2D, were urinary tract infections, genital mycotic infections, and hypoglycemia.
- In patients without T2D, the most commonly reported adverse reactions were urinary tract infections, genital mycotic infections, and hypoglycemia.

### Safety profile of FARXIGA in DAPA-HF across T2D

- The safety population included patients receiving ≥1 dose of trial medication: FARXIGA n=2368 and placebo n=2368.
- In patients without T2D, the incidence of adverse reactions associated with FARXIGA treatment was 6.3% vs 6.2% vs 6.2%.
- In patients with T2D, the incidence of adverse reactions associated with FARXIGA treatment was 6.3% vs 6.2% vs 6.2%.

### References