Brand Name: Komboglyze

Generic: saxagliptin and metformin HCl

Type: small molecule Year Accepted/Phase:

Type 2 Diabetes: 2014 Heart Failure: 2020

Chronic Kidney Disease: 2021

## Mechanism:

Dapagliflozin inhibits SGLT2 in the proximal renal tubules, reducing glucose reabsorption and increasing urinary glucose excretion, leading to lower blood glucose levels, reduced weight, and improved cardiovascular and renal outcomes.

## **Chemical Structure:**

# Indication:

Farxiga is indicated for the treatment of type 2 diabetes mellitus, heart failure with reduced ejection fraction, and chronic kidney disease.

#### **Clinical trials:**

### DAPA-HF Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/31535829/

**Purpose:** Assess the efficacy and safety of dapagliflozin in reducing the risk of cardiovascular death or worsening heart failure in patients with heart failure with reduced ejection fraction (HFrEF).

Dates: Conducted from 2017 to 2019.

**Results:** The DAPA-HF trial demonstrated that dapagliflozin significantly reduced the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits compared to placebo in patients with HFrEF, regardless of diabetes status.

**Impact:** These results supported the approval of Farxiga for the treatment of heart failure with reduced ejection fraction.

#### **DECLARE-TIMI 58 Trial (Phase III)**

Pubmed: https://pubmed.ncbi.nlm.nih.gov/30415602/

**Purpose:** Evaluate the cardiovascular safety and efficacy of dapagliflozin in reducing major adverse cardiovascular events (MACE) in patients with type 2 diabetes and established cardiovascular disease or multiple risk factors.

Dates: Conducted from 2013 to 2018.

**Results:** The DECLARE-TIMI 58 trial showed that dapagliflozin reduced the risk of cardiovascular death and hospitalization for heart failure, although it did not significantly reduce the risk of MACE compared to placebo. The trial also demonstrated a favorable renal safety profile.

**Impact:** These results provided evidence of the cardiovascular benefits of Farxiga in patients with type 2 diabetes.

## **DAPA-CKD Trial (Phase III)**

Pubmed: https://pubmed.ncbi.nlm.nih.gov/32970396/

**Purpose:** Investigate the efficacy and safety of dapagliflozin in patients with

chronic kidney disease (CKD), with or without type 2 diabetes.

**Dates:** Conducted from 2017 to 2020.

**Results:** The DAPA-CKD trial demonstrated that dapagliflozin significantly reduced the risk of worsening kidney function, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in patients with CKD.

**Impact:** These results supported the approval of Farxiga for the treatment of chronic kidney disease.