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## **Efficacy and Safety of Finerenone in Patients With Chronic Kidney Disease and Type 2 Diabetes by Diuretic Use: A FIDELITY Analysis**

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### **Abstract**

**Background:** Diuretics are used to treat hypertension and HF in patients with CKD. Diuretics alter potassium levels, which are associated with CV outcomes.

**Objective:** To assess the effect of finerenone, a non-steroidal MRA, on CV and safety outcomes by baseline diuretic use in the FIDELITY dataset.

**Methods:** In FIDELITY, a pooled analysis of the FIDELIO-DKD (NCT02540993) and FIGARO-DKD (NCT02545049) trials, patients with CKD and T2D who were optimally treated with RASi were randomized to finerenone or placebo. Patients were categorized by baseline diuretic use. A composite CV outcome (CV death, non-fatal myocardial infarction, non-fatal stroke, or hospitalization for HF) and treatment-emergent adverse events were assessed.

**Results:** Across 13,026 patients, 51.5% were treated with diuretics at baseline (21.5% on loop and 24.2% on thiazide diuretics). The composite CV outcome was reduced with finerenone vs placebo, irrespective of baseline diuretic use (Yes: HR: 0.86; 95% CI: 0.77-0.97; No: HR: 0.86; 95% CI: 0.74-1.00;  $P_{interaction}=0.95$ ). On-treatment analysis showed concomitant diuretic use with study treatment was mainly constant among patients during the follow-up period. Hyperkalemia rates for patients on finerenone were comparable by diuretic use (Yes: 13.8% vs. 5.7% for placebo; No: 14.3% vs. 8.3% for placebo). Incidence of hyperkalemia leading to hospitalization or discontinuation of study drug for both treatment groups was low irrespective of diuretic use.

**Conclusion:** Finerenone was associated with a reduced risk of CV outcomes and there was a low incidence of hyperkalemia leading to hospitalization in patients with CKD and T2D, irrespective of baseline diuretic use.

**Keywords:** Cardiovascular, diuretic, finerenone, hyperkalemia, hypertension

**Abbreviations:** Chronic kidney disease (CKD), heart failure (HF), renin-angiotensin system inhibitors (RASi), mineralocorticoid receptor antagonist (MRA), type 2 diabetes (T2D)

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**Ethical approval:** Both the FIGARO-DKD and FIDELIO-DKD studies complied with the Declaration of Helsinki and approval was obtained from the required ethical committees and regulatory authorities. All patients provided written informed consent.

**Disclosures/Conflict of Interest:**

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