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Effect of Finerenone in Patients With Chronic Kidney Disease and Type 2 Diabetes by Baseline Anemia Status: A FIDELITY Analysis

Author/s: Ajay Singh, MBBS[1] Stefan D. Anker, MD[2,3] Gerasimos Filippatos, MD[4] Bertram Pitt, MD[5] Peter Rossing, MD[6,7] Luis M. Ruilope, MD[8-10] Alfredo E. Farjat, PhD[11] Glen James, PhD[12] Youssef M.K. Farag, MD,PhD[13] Luke Roberts, MBBS PhD[14] George L. Bakris, MD[15] Tram Knecht, PharmD,[13] on behalf of the FIDELIO-DKD and FIGARO-DKD Investigators

Organizations/Affiliations:

[1]Renal Division, Harvard Medical School, Harvard University, Boston, MA, USA
[2]Department of Cardiology (CVK), and Berlin Institute of Health Center for Regenerative Therapies, German Centre for Cardiovascular Research Partner Site Berlin, Charité Universitätsmedizin, Berlin, Germany
[3]Institute of Heart Diseases, Wrocław Medical University, Wrocław, Poland
[4]National and Kapodistrian University of Athens, School of Medicine, Department of Cardiology, Attikon University Hospital, Athens, Greece
[5]Department of Medicine, University of Michigan School of Medicine, Ann Arbor, MI, USA
[6]Steno Diabetes Center Copenhagen, Herlev, Denmark
[7]Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark
[8]Cardiorenal Translational Laboratory and Hypertension Unit, Institute of Research imas12, Madrid, Spain
[9]CIBER-CV, Hospital Universitario 12 de Octubre, Madrid, Spain
[10]Faculty of Sport Sciences, European University of Madrid, Madrid, Spain
[11]Research and Development, Clinical Data Sciences and Analytics, Bayer PLC, Reading, UK
[12]Integrated Evidence Generation and Business Innovation, Bayer PLC, Reading, UK
[13]Cardiovascular and Renal United States Medical Affairs, Bayer U.S. LLC, Whippany, NJ, USA
[14]Clinical Development, Bayer PLC, Reading, UK
[15]Department of Medicine, University of Chicago Medicine, Chicago, IL, USA

Abstract

Background: Despite anemia being associated with CKD progression, adverse CV events and premature mortality in patients with CKD, management of these patients remains suboptimal.

Objective: Post-hoc analysis of FIDELITY investigating the efficacy and safety of finerenone, a non-steroidal MRA, versus placebo in patients categorized by baseline anemia status.

Methods: Patients with CKD and T2D, who were optimally treated with RASi, were randomized to finerenone or placebo. A CV composite outcome (CV death, non-fatal MI, non-fatal stroke, or hospitalization for HF), kidney composite outcome (kidney failure, sustained eGFR decrease ≥57%, or kidney-related death), hospitalization for HF, and all-cause mortality were assessed by baseline anemia status. Treatment-emergent adverse events were also assessed.

Results: Of 13,007 patients, 4293 (33.0%) had anemia at baseline. The risk reduction on CV composite outcome was nominally significant with finerenone versus placebo in patients with anemia at baseline (HR 0.76;95% CI 0.65-0.88) but not in those without (HR 0.93;95% CI 0.82-1.04; $P_{interaction}$=0.04). Finerenone also reduced the risk of kidney composite outcome, all-cause mortality, and hospitalization for HF versus placebo, with no heterogeneity between the treatment groups and across anemia subgroups. Incidence of hyperkalemia was higher in patients with anemia at baseline in both treatment arms (21.2% finerenone vs 11.5% placebo) versus those without (10.5% finerenone vs 4.6% placebo).

Conclusions: In patients with CKD and T2D, finerenone's effect on the CV composite outcome was modified by anemia. Finerenone' s effect on the kidney composite outcome, all-cause mortality, and hospitalization for HF was similar irrespective of baseline anemia status.

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Abbreviations: Chronic kidney disease (CKD), estimated glomerular filtration rate (eGFR), mineralocorticoid receptor antagonist (MRA), renin–angiotensin system inhibitor (RASi), type 2 diabetes (T2D)

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Ethical approval:
FIDELITY was a pooled analysis of the FIDELIO-DKD (NCT02540993) and FIGARO-DKD (NCT02545049). 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:

This study was first presented at ASN 2023.

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