Finerenone benefits patients with diabetes across spectrum of kidney disease

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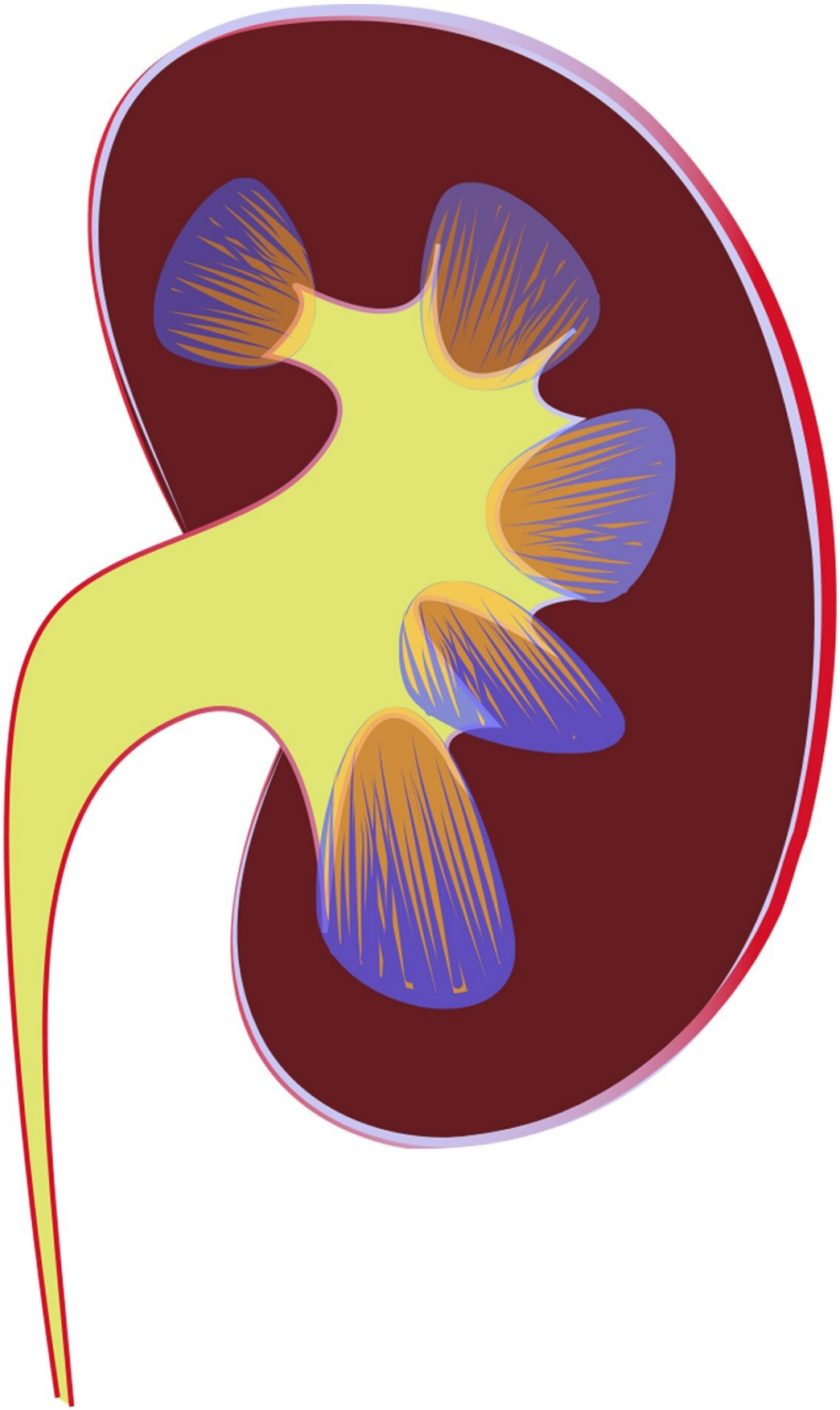

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Finerenone reduces the risk of cardiovascular and renal outcomes compared to placebo in patients with type 2 diabetes and all stages of kidney disease. That's the finding of late breaking research presented in a Hot Line session today at ESC Congress 2021.

The nonsteroidal mineralocorticoid receptor antagonist finerenone has been evaluated in two trials of patients with chronic kidney disease and type 2 diabetes. The FIDELIO-DKD trial previously reported that the drug slowed progression of kidney disease and improved cardiovascular outcomes in patients with predominantly advanced kidney disease and type 2 diabetes. The results of FIGARO-DKD, reported at ESC Congress 2021, showed that finerenone reduced the risk of cardiovascular events in patients with mild-to-moderate kidney disease and type 2 diabetes.

FIDELITY was a prespecified meta-analysis combining individual patient data from FIDELIO-DKD and FIGARO-DKD. The aim was to evaluate the relationship between the stage of kidney disease and the efficacy of finerenone on composite cardiovascular and renal endpoints. Stages of kidney disease were defined according to categories of estimated glomerular filtration rate (eGFR) and urine albumin-to-creatinine ratio (UACR).

Study author Professor Gerasimos Filippatos of the National and Kapodistrian University of Athens Medical School, Greece said: "More than 13,000 patients were included in this analysis, enabling more robust estimates of the cardiorenal efficacy and safety of finerenone than either

trial alone. In addition, the analysis encompassed the full range of kidney disease severity experienced by patients with type 2 diabetes."

Both trials enrolled adults with type 2 diabetes and chronic kidney disease treated with optimized renin-angiotensin system blockade and with a serum potassium of 4.8 mmol/L or below. Patients with symptomatic chronic heart failure with reduced ejection fraction were excluded. Participants were randomized 1:1 to receive oral finerenone or placebo, once daily.

The primary endpoint for this analysis was time to first occurrence of a composite of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke or hospitalization for heart failure, and its relationship with eGFR and UACR categories. The secondary endpoint was time to first occurrence of a composite of kidney failure, decrease in eGFR by 57% or more from baseline sustained for at least four weeks, or renal death, and its relationship with eGFR and UACR categories.

A total of 13,026 patients were followed-up for a median of 3.0 years. The composite cardiovascular endpoint occurred in 825 (12.7%) patients receiving finerenone and 939 (14.4%) receiving placebo. Finerenone reduced the risk of this outcome by 14% compared with placebo (hazard ratio [HR] 0.86; 95% confidence interval [CI] 0.78–0.95; p=0.0018).

The composite kidney endpoint occurred in 360 (5.5%) patients receiving finerenone and 465 (7.1%) receiving placebo. The risk of this outcome was 23% lower with finerenone than placebo (HR 0.77; 95% CI 0.67–0.88; p=0.0002). All components of the composite kidney outcome were significantly lower with finerenone than placebo, except renal death which occurred too infrequently to make a comparison between groups.

Regarding safety, outcomes were generally similar between treatment

arms. Hyperkalaemia was more common with finerenone (14.0%) than placebo (6.9%). However, permanent discontinuation of treatment due to hyperkalaemia was infrequent (1.7% in the finerenone group versus 0.6% in the placebo group).

Professor Filippatos said: "The FIDELITY analysis demonstrates that finerenone reduced the risk of cardiovascular and kidney outcomes compared with placebo across the spectrum of chronic kidney disease in patients with type 2 diabetes. The cardiovascular benefits of the drug were consistent across eGFR and UACR categories, indicating that treatment should be initiated in the early stages of renal disease."

More information: FIDELITY Analysis: finerenone in mild-to-severe chronic kidney disease and type 2 diabetes.

George L. Bakris et al, Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes, *New England Journal of Medicine* (2020). DOI: 10.1056/NEJMoa2025845

Gerasimos Filippatos et al, Finerenone and Cardiovascular Outcomes in Patients With Chronic Kidney Disease and Type 2 Diabetes, *Circulation* (2020). DOI: 10.1161/CIRCULATIONAHA.120.051898

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