Clinical trial shows experimental drug safely slows progression of diabetic kidney disease

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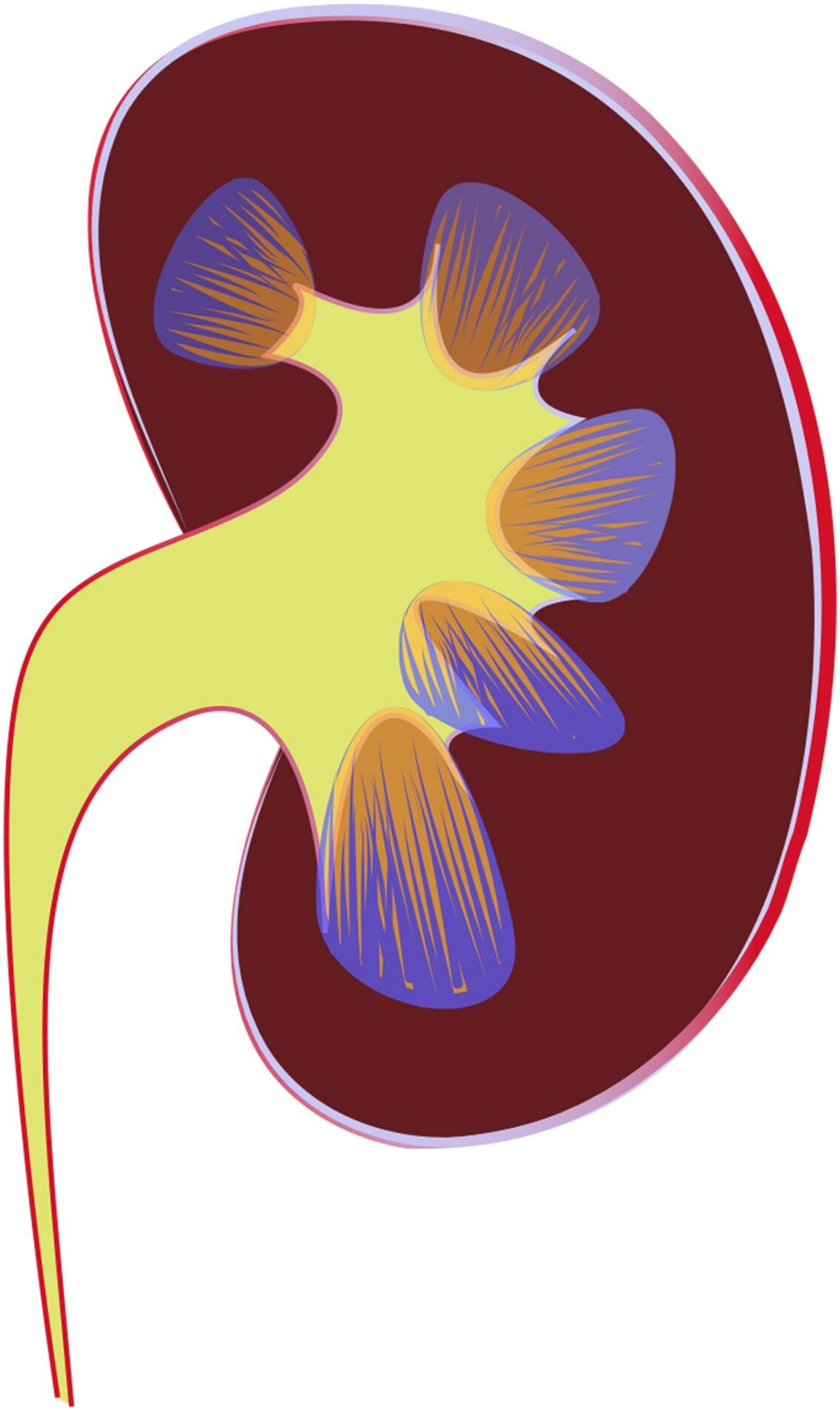

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The findings, simultaneously published in the *New England Journal of Medicine* and presented at the American Society of Nephrology's Kidney Week 2020 conference, show the investigational drug finerenone had tangible renal and cardiovascular benefits for patients with chronic kidney disease and type 2 diabetes.

The 5,700-person phase III trial was led by George Bakris, MD, Professor of Medicine at the University of Chicago and Director of the Comprehensive Hypertension Center at the University of Chicago Medicine. Taking place at more than 1,000 sites in 48 countries, the study was the largest-ever research effort into the disease that affects millions of people in the U.S. alone. More than 1/4 of adults with diabetes will eventually develop chronic kidney disease, making diabetes the leading cause of kidney failure.

"We now have evidence that doctors can safely slow diabetic kidney disease progression and reduce cardiovascular event rates using finerenone, a novel nonsteroidal mineralocorticoid receptor blocker, not yet approved by the FDA. This is very important for a group of patients who've historically had very few options," said Bakris. "This promising target for a new therapy means patients are able to delay dialysis and, in turn, further delay the possible need for kidney transplants. The reduction in cardiovascular events is an added bonus to slowing kidney disease progression."

Finerenone, which is made by Bayer, is a non-steroidal, selective mineralocorticoid receptor (MR) antagonist. The drug is not yet

approved for use, but is being investigated in a number of clinical trials, including FIGARO that will be finished next year on cardiovascular outcomes. It directly targets and blocks receptors that contribute to inflammation and scarring of the heart and kidney. Kidneys filter waste and water from the body and also play role in controlling blood pressure and when they're damaged can lead to a backup of waste and fluid in the body.

Called FIDELIO-DKD (FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease), the study showed the drug was significantly better than a placebo, slowing the progression of kidney disease by 18% over a median of 2.6 years compared to current standard of care.

While patients who received finerenone did report higher levels of potassium (18% versus 9% with a placebo), serious potassium-related side effects requiring study discontinuation were infrequent and occurred in 2.8% of patients versus 0.9% of the control group. High levels of potassium can lead to cardiac rhythm problems.

Bayer announced earlier this year that the trial met its composite primary renal endpoint and its composite key secondary cardiovascular endpoint. But full findings of the trial weren't released until Oct. 23. The trial was randomized, double-blind and placebo-controlled.

More information: George L. Bakris et al. Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes. *NEJM* October 23, 2020.
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