



News Release

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Bayer’s Finerenone Meets Primary Endpoint in Phase III FIGARO-DKD Cardiovascular Outcomes Study in Patients With Chronic Kidney Disease and Type 2 Diabetes

- Finerenone significantly reduced the risk of the composite primary endpoint of cardiovascular death and non-fatal cardiovascular events versus placebo when added to standard of care¹
- FIGARO-DKD is the second positive Phase III study within the finerenone study program in CKD and T2D to meet its primary endpoint^{1,2,3}

Whippany, N.J., May 10, 2021 – Bayer’s Phase III cardiovascular outcomes study FIGARO-DKD, evaluating the efficacy and safety of the investigational drug finerenone versus placebo when added to standard of care in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) has met its primary endpoint. The study showed finerenone significantly reduced the composite risk of time to first occurrence of cardiovascular (CV) death or non-fatal CV events (myocardial infarction, stroke, or hospitalization for heart failure). The Phase III FIGARO-DKD study included more patients with earlier stage CKD and T2D compared to the FIDELIO-DKD study, which was the first of two Phase III studies investigating finerenone in patients with CKD and T2D.^{1,3}

“Up to 40 percent of people with type 2 diabetes develop chronic kidney disease, and they are at high risk of experiencing cardiovascular events, as well as progressing to kidney failure,”^{4,5,6,7} said Prof. Luis M. Ruilope, Professor at the Public Health and Preventative Medicine department of the Autonoma University and co-principal investigator of the FIGARO-DKD trial. “The FIGARO-DKD study delivers important insights into the potential effects on cardiovascular outcomes of finerenone in the management of people with chronic kidney disease and type 2 diabetes.”

“With the positive outcome of the composite primary endpoint of the FIGARO-DKD trial, we have reached a significant milestone for finerenone by completing the largest Phase III clinical trial program to date focusing on chronic kidney disease and type 2 diabetes across a broad range of disease severity,”^{1,2,3} said Dr. Christian Rommel, Member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Head of Research and Development. “We are pleased to see that the FIGARO-DKD data further support evidence generated in the FIDELIO-DKD trial with respect to reducing the risk of the composite of cardiovascular death and non-fatal cardiovascular events or outcomes in patients with chronic kidney disease and type 2 diabetes.”^{1,8}

The Phase III program with finerenone in CKD and T2D randomized about 13,000 patients across a broad range of disease severity, including those with early kidney damage and more advanced stages of kidney disease.^{2,3} FIGARO-DKD is a randomized, double-blind, placebo-controlled, parallel-group, event-driven Phase III study that investigated finerenone versus placebo in patients with CKD and T2D.^{3,9} The study randomized approximately 7,400 patients from more than 1,000 sites across 47 countries worldwide.^{3,9} Patients were randomized to receive either finerenone 10 mg or 20 mg orally once daily or placebo when added to standard of care, including blood glucose lowering therapies and maximum tolerated dose of the guideline directed therapies angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin II receptor blockers (ARBs).^{3,9}

The new drug application (NDA) currently under review by the U.S. FDA for Priority Review was based on positive data from the Phase III FIDELIO-DKD study. Results from that trial were presented at the American Society of Nephrology’s (ASN) Kidney Week Reimagined 2020, and simultaneously published in the [New England Journal of Medicine](#) in October 2020.⁸ The clinical data from FIGARO-DKD will be presented at an upcoming scientific meeting.

About Finerenone

Finerenone (BAY 94-8862) is an investigational, non-steroidal, selective mineralocorticoid receptor antagonist (MRA) that has been shown to reduce many of the harmful effects of mineralocorticoid receptor (MR) overactivation.¹⁰ Mineralocorticoid receptor overactivation is a driver of kidney and cardiovascular damage through inflammatory and fibrotic processes.^{11,12} In 2015, the Food and Drug Administration granted Fast Track designation to finerenone.

About Chronic Kidney Disease in Type 2 Diabetes

Chronic kidney disease is a life-threatening condition that is under-recognized. CKD is one of the most frequent complications arising from diabetes and is also an independent risk factor of cardiovascular disease.¹³ In this press release, the terms “Diabetic Kidney Disease” and “Chronic Kidney Disease in Type 2 Diabetes” are being used synonymously. Approximately 40 percent of all patients with T2D develop CKD.¹⁴ Despite guideline-directed therapies, patients with CKD and T2D remain at high risk of CKD progression and cardiovascular events.^{13,15} In 2013, diabetes led to more than 51,000 new cases of kidney failure in the U.S.¹⁶ Chronic kidney disease in T2D is the main cause of end stage kidney disease and kidney failure and at advanced stages, patients may need dialysis or a kidney transplant to stay alive.^{17,18} Mineralocorticoid receptor over-activation is known to trigger detrimental processes (e.g., inflammation and fibrosis) in kidneys and heart in patients with CKD and T2D.¹¹

About Bayer’s Commitment in Cardiovascular and Kidney Diseases

Bayer is an innovation leader in the area of cardiovascular diseases, with a long-standing commitment to delivering science for a better life by advancing a portfolio of innovative treatments. The heart and the kidneys are closely linked in health and disease, and Bayer is working in a wide range of therapeutic areas on new treatment approaches for cardiovascular and kidney diseases with high unmet medical needs. The cardiology franchise at Bayer already includes a number of products and several other compounds in various stages of preclinical and clinical development. Together, these products reflect the company’s approach to research, which prioritizes targets and pathways with the potential to impact the way that cardiovascular diseases are treated.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

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