



Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
www.bayer.com/en/media

News Release

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Late-Breaking data from pooled analysis INFINITY presented at 63rd ERA Congress:

Finerenone significantly reduced the risk of kidney disease progression and cardiovascular outcomes in broad patient populations with CKD

- In INFINITY, finerenone significantly reduced the risk of chronic kidney disease (CKD) progression, including kidney failure, by 24% versus placebo in addition to standard of care in patients with CKD, regardless of glycemic status, underlying etiology, or level of kidney function at baseline
 - Finerenone also significantly reduced the risk of the main composite cardiovascular outcome of heart failure hospitalisation or cardiovascular death by 20% versus placebo
 - INFINITY is a prespecified pooled analysis of the completed Phase III studies FIDELIO-DKD, FIGARO-DKD, and FIND-CKD including more than 14,500 patients; and the largest analysis of efficacy and safety of finerenone on kidney, cardiovascular, and safety outcomes across a diverse patient population with diabetic and non-diabetic CKD with differing risks of kidney failure, cardiovascular events and hyperkalemia
 - Results from INFINITY were simultaneously published in the [LANCET](#)
 - Chronic Kidney Disease (CKD) represents a major global health challenge, affecting 850 million people worldwide – in fact, as the ninth leading cause of death, it results in 1.5 million fatalities each year, translating to one death every 20 seconds
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Berlin, June 5, 2026 – The INFINITY prespecified pooled analysis of the three completed pivotal Phase III clinical trials with finerenone in chronic kidney disease associated with type 2 diabetes and non-diabetic patient populations (namely FIDELIO-DKD, FIGARO-DKD, and FIND-CKD) showed that over a median follow-up of 3 years, finerenone reduced the risk of the main composite kidney outcome of kidney failure or sustained $\geq 57\%$ decline in estimated glomerular filtration rate (eGFR) by 24% compared to placebo

(HR 0.76 [95% CI, 0.68-0.86; $p < 0.0001$]). Finerenone also reduced the risk of kidney failure alone, by 15% versus placebo (HR 0.85 [95% CI, 0.74-0.98; $p = 0.03$]). Finerenone reduced the main composite cardiovascular outcome of heart failure hospitalisation or cardiovascular death versus placebo by 20% (HR 0.80 [95% CI, 0.70-0.91; $p = 0.0006$]). The risk of the main cardiovascular-kidney outcome (a composite of sustained $\geq 57\%$ decline in eGFR or kidney failure, heart failure hospitalization or cardiovascular death) was also lower with finerenone compared with placebo (HR 0.77 [95% CI, 0.70-0.85; $p < 0.0001$]). The findings from INFINITY were presented today during a Late-Breaking Clinical Trials session at the 63rd ERA Congress 2026, and simultaneously published in the [LANCET](#).

“The INFINITY pooled analysis provides a comprehensive evaluation of the effects of finerenone on kidney and cardiovascular outcomes across a diverse patient population with diabetic and non-diabetic chronic kidney disease,” said Brendon L. Neuen, Lead Global Clinical Trialist at The George Institute for Global Health and a Staff Specialist Nephrologist and Director of Kidney Trials at Royal North Shore Hospital, Sydney, Australia. “The consistency of benefits of finerenone, irrespective of glycaemic status, cause of kidney disease, or kidney function, marks an important advance in our ability to protect patients from the twin threats of kidney failure and cardiovascular disease, and support the extension of finerenone’s role to a substantially broader patient population with chronic kidney disease.”

“Based on the totality of randomized clinical evidence and the consistent benefits seen with finerenone in chronic kidney disease, these data across more than 14,500 patients underscore the potential for finerenone to improve multiple kidney-cardiovascular outcomes in broad, high-risk patient populations with chronic kidney disease, regardless of the underlying cause,” said Dr. Christian Rommel, Global Head of Research and Development at Bayer’s Pharmaceuticals Division. “The data from INFINITY reinforce the role of finerenone as a well-tolerated, foundational treatment option addressing a shared pathway involved in kidney disease progression and cardiovascular damage across patients with diabetic and non-diabetic CKD.”

The INFINITY pooled analysis showed that finerenone was well-tolerated across diverse diabetic and non-diabetic CKD patient populations, which is consistent with the well-established safety profile of finerenone.

With more than 14,500 patients randomized, INFINITY is the largest analysis of efficacy and safety of finerenone in both patients with CKD associated with type 2 diabetes (T2D) and patients with CKD with diverse non-diabetic underlying etiologies. The analysis extends the already existing evidence base for finerenone beyond CKD associated with T2D to non-diabetic CKD, demonstrating consistent cardiovascular- and kidney-protective effects across a diverse patient population with CKD with differing risks of kidney failure, cardiovascular events and hyperkalemia.

Mineralocorticoid receptor (MR) overactivation is a shared pathway across diabetic and non-diabetic CKD populations, promoting inflammation, fibrosis, and CKD progression. Finerenone is a selective, non-steroidal mineralocorticoid receptor antagonist (nsMRA) and the first drug targeting the MR pathway that in five pivotal Phase III studies has demonstrated cardiovascular and/or kidney benefits, respectively, in patients with HF with left ventricular ejection fraction (LVEF) $\geq 40\%$, patients with CKD associated with type 2 diabetes, patients with CKD associated with type 1 diabetes, and patients with non-diabetic CKD.

About Kerendia™ / Firalta™ (finerenone)

Kerendia™ and Firalta™ are globally protected trademarks for finerenone. Finerenone is a selective, non-steroidal mineralocorticoid receptor antagonist (nsMRA) that has been shown to block harmful effects of MR overactivation. MR overactivation contributes to chronic kidney disease (CKD) progression and cardiovascular damage which can be driven by metabolic, hemodynamic, or inflammatory and fibrotic factors.

Since 2021, finerenone is marketed as Kerendia™ or, in selected countries, as Firalta™, and approved for the treatment of adult patients with CKD associated with type 2 diabetes (T2D) in more than 100 countries worldwide, including in China, Europe, Japan, and the U.S. Following priority review designation, finerenone has been approved for the treatment of heart failure with LVEF $\geq 40\%$ in the U.S. since July 2025. In the EU, Japan, several other markets, and since recently in China, finerenone is also approved in heart failure with LVEF $\geq 40\%$. Applications for marketing authorization in HF with LVEF $\geq 40\%$ have been filed in additional markets.

The clinical study program with finerenone, FINEOVATE, currently comprises twelve Phase III studies with dedicated programs in CKD and HF respectively. The THUNDERBALL CKD program consists of the completed Phase III studies FIDELIO-

DKD, FIGARO-DKD, FIND-CKD, and FINE-ONE, and the Phase II study CONFIDENCE; as well as the ongoing Phase III studies in pediatric patient populations FIONA, and FIONA-OLE. The MOONRAKER program includes the completed pivotal Phase III study FINEARTS-HF, the ongoing investigator-sponsored, collaborative studies REDEFINE-HF, CONFIRMATION-HF, and FINALITY-HF, as well as the ongoing Phase III studies in pediatric patient populations, FIORE and FIORELLO.

About INFINITY

INFINITY is a prespecified pooled analysis of the completed Phase III studies FIDELIO-DKD, FIGARO-DKD, and FIND-CKD including more than 14,500 patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D) and patients with CKD of diverse non-diabetic underlying etiologies.

INFINITY investigated the efficacy and safety of finerenone on kidney, cardiovascular, and safety outcomes across a diverse patient population with diabetic and non-diabetic CKD with differing risks of kidney failure, cardiovascular events and hyperkalemia. The main composite kidney outcome was kidney failure, or a sustained $\geq 57\%$ decline in eGFR relative to baseline, corresponding approximately to a doubling of serum creatinine. Kidney failure was defined as sustained eGFR < 15 ml/min/1.73 m² or initiation of chronic dialysis or kidney transplantation.

Further outcomes included kidney failure alone; the main composite cardiovascular outcome of heart failure hospitalisation or cardiovascular death; the main composite kidney-cardio outcome including sustained $\geq 57\%$ decline in eGFR or kidney failure, heart failure hospitalization or cardiovascular death.

Summary of key findings

INFINITY included 14,574 adults with CKD (mean age 63.7 years; mean eGFR 56.4 ml/min/1.73 m²; median urinary albumin to creatinine ratio (UACR) 567 mg/g).

- Primary composite kidney outcome (kidney failure or sustained $\geq 57\%$ decline in eGFR): Finerenone reduced risk by 24% versus placebo (HR 0.76 [95% CI; 0.68-0.86; $p < 0.0001$).
- Kidney failure alone: Finerenone reduced risk by 15% (HR 0.85 [95% CI; 0.74-0.99; $p = 0.030$).

- Primary composite cardiovascular outcome (hospitalisation for heart failure or cardiovascular death): Finerenone reduced risk by 20% versus placebo (HR 0.80 [95% CI; 0.70-0.91; p=0.0006]).
- Composite kidney-cardiovascular outcome (sustained $\geq 57\%$ decline in eGFR from baseline over ≥ 4 weeks or kidney failure, or hospitalization for heart failure or CV death (HR 0.77 [95% CI; 0.70-0.85; p<0.0001])
- Finerenone also reduced the risk of:
 - o Heart failure hospitalisation (HR 0.78 [95% CI; 0.66-0.92; p=0.0024]).
 - o Cardiovascular death (HR 0.82 [95% CI; 0.67-0.999; p=0.049]).
 - o All cause mortality (HR 0.88 [95% CI; 0.79-0.99; p=0.026]).
 - o Dialysis or Kidney transplantation (HR 0.77 [95% CI; 0.64-0.94; p=0.0089])

Treatment effects were consistent across prespecified subgroups including glycaemic status (diabetic and non-diabetic CKD), cause of kidney disease, baseline eGFR, baseline albuminuria, and baseline use of SGLT-2 inhibitors.

The INFINITY pooled analysis showed that finerenone was well-tolerated across diverse diabetic and non-diabetic CKD patient populations, which is consistent with the well-established safety profile of finerenone.

About Chronic Kidney Disease

CKD is a common and potentially deadly condition that is widely underrecognized. CKD progresses silently and unpredictably, with many symptoms not appearing until the disease is well-advanced. Chronic Kidney Disease (CKD) represents a major global health challenge, affecting 850 million people worldwide – in fact, as the ninth leading cause of death, it results in 1.5 million fatalities each year, translating to one death every 20 seconds. In the U.S., 1 in 3 adults is at risk for the disease. At advanced stages of CKD, patients may need dialysis or a kidney transplant to stay alive. Healthy kidneys act as the body's filter, removing waste products from the blood. They also control how much water and electrolytes are in the body, regulating blood pressure. As kidney function goes down, patients may experience a range of symptoms including leg swelling, tiredness in the day, nausea, muscle cramps, joint pain and confusion, trouble focusing, memory problems. Major underlying causes of CKD include diabetes, hypertension, and glomerular diseases such as immunoglobulin A nephropathy, focal segmental glomerulosclerosis and membranous nephropathy.

About Bayer's Commitment in Cardiovascular and Kidney Diseases

Bayer is a leader in the area of cardiology and is advancing a portfolio of innovative treatments. The heart and the kidneys are closely linked in health and disease, and Bayer is working on new treatment approaches for cardiovascular and kidney diseases with high unmet medical needs. The strategy is to unlock the strong potential of the future cardiovascular market by transforming Bayer's portfolio into precision cardiology, addressing the high disease burden, and driving long-term growth. Bayer's portfolio already includes several innovative products and 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 and kidney diseases are treated.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating 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 2025, the Group employed around 88,000 people and had sales of 45.6 billion euros. R&D expenses amounted to 5.8 billion euros. For more information, go to www.bayer.com.

Contact for media inquiries:

Dr. Daniela Esser, phone +49 30 2215-41588

Email: daniela.esser@bayer.com

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Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at

www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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