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News Release

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Late-Breaking data from FINE-ONE Phase III study presented at ASN Kidney Week 2025

Finerenone showed statistically significant reduction of UACR in adults with chronic kidney disease associated with type 1 diabetes

- Finerenone is the first medicine in over 30 years to provide positive results in a Phase III study addressing the high risk of kidney disease progression and cardiovascular events in adults with chronic kidney disease (CKD) associated with type 1 diabetes (T1D)
- In the global FINE-ONE Phase III study, finerenone significantly reduced urine albumin-to-creatinine ratio (UACR) by 25% from baseline (ratio to baseline) over 6 months compared to placebo
- CKD associated with T1D is a major public health challenge: 30% of people with T1D develop CKD, and CKD associated with T1D significantly increases the risk of kidney failure and cardiovascular events, contributing to CKD being a leading cause of death in T1D
- Treatment options in people with CKD associated with T1D are limited, and residual risk remains high in these patients despite guideline-recommended therapies to control hyperglycemia, hypertension, and albuminuria

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Berlin, November 6, 2025 – Bayer today announced results from the pivotal Phase III FINE-ONE study, demonstrating that finerenone (Kerendia™/ Firialta™) in addition to standard of care is superior to placebo in showing a statistically significant reduction in urine albumin-to-creatinine ratio (UACR) from baseline (ratio to baseline) over 6 months in adults with chronic kidney disease (CKD) associated with type 1 diabetes (T1D). Elevated UACR is associated with a higher risk of kidney disease progression and kidney failure, and is a predictor of cardiovascular events. Reduction of UACR with finerenone in the pivotal Phase III studies in CKD in type 2 diabetes (FIDELIO-DKD, FIGARO-DKD) was strongly associated with delay of kidney disease progression and kidney failure, as well as with a reduction of cardiovascular events. The FINE-ONE findings were presented

today as “Featured High-Impact Clinical Trial” during the Opening Plenary session of the American Society of Nephrology’s (ASN) Kidney Week 2025.

“Patients living with type 1 diabetes and chronic kidney disease face an increased risk of kidney failure and cardiovascular disease, impacting quality of life and life expectancy,” said Hiddo Lambers Heerspink, Professor of Clinical Trials and Personalized Medicine at the University Medical Center Groningen, Netherlands, and Chair of the study’s Steering Committee. “UACR reduction is highly correlated with a reduction in kidney and cardiovascular events. The positive results of the FINE-ONE study represent a landmark moment and give hope to patients with chronic kidney disease associated with type 1 diabetes who currently have very limited treatment options.”

In FINE-ONE, finerenone significantly reduced the primary endpoint of relative change in UACR by 25% (percentage reduction, least squares geometric mean (LSGM) ratio 0.75 [95% CI, 0.65-0.87; p=0.0001]) from baseline over 6 months versus placebo. At any time post-baseline, 81 out of 119 participants (68.1%) in the finerenone arm, versus 54 out of 116 participants (46.6%) in the placebo arm achieved at least a 30% reduction in UACR, a threshold established by the American Diabetes Association (ADA) as being associated with slower CKD progression in patients with CKD associated with type 2 diabetes. Based on the outcome of FINE-ONE, the non-steroidal mineralocorticoid receptor antagonist (nsMRA) finerenone is the first medicine since the 1990s to provide positive results in a Phase III study addressing the high risk of kidney disease progression and cardiovascular events in patients with CKD associated with T1D.

"People with type 1 diabetes and chronic kidney disease face an immense burden due to their increased risk for both kidney and cardiovascular events," said Jonathan Rosen, PhD, Research Director at Breakthrough T1D, the leading global type 1 diabetes research and advocacy organization. "Breakthrough T1D remains committed to collaborating with Bayer to improve kidney care for people with type 1 diabetes."

CKD affects 30% of people with T1D and approximately one in four of these individuals will progress to end-stage kidney disease. In 2025, more than 9.5 million people are living with T1D worldwide, with prevalence projected to rise to between 13.5 - 17.4 million in 2040. People with both T1D and CKD face a significantly increased risk of kidney failure and cardiovascular disease (CVD). In the U.S., 1.4 million adults aged 20 years or older are living with type 1 diabetes, representing 5.2% of all US adults with diagnosed

diabetes. More than half of new T1D diagnoses in the U.S. occur in people aged 20 and older, and around 85% of these cases arise in people with no known family history of the condition.

“UACR is an important predictor of kidney and cardiovascular events in chronic kidney disease associated with diabetes, with elevated levels indicating worsening kidney damage. For more than three decades, no kidney-specific disease modifying therapies have been approved in chronic kidney disease associated with type 1 diabetes,” said Dr. Christian Rommel, Global Head of Research and Development at Bayer’s Pharmaceuticals Division. “Finerenone has demonstrated its ability to reduce UACR in patients with CKD associated with T1D, and we are excited about the prospect of offering a potential new treatment option for these patients, whose condition has been under-researched for so long.”

The results of the FINE-ONE study are consistent with and add to the robust body of evidence of finerenone, showing a significant reduction in UACR over 6 months. There is a strong association between elevated UACR (albuminuria) and kidney disease progression in both types of diabetes, and UACR reduction is highly correlated with a reduction in kidney and cardiovascular events. Data from the FIDELITY pooled analysis of the Phase III FIDELIO-DKD and FIGARO-DKD studies in patients with CKD associated with type 2 diabetes showed that more than 80% of the kidney benefit of finerenone was explained by UACR reduction. Finerenone is a non-steroidal, selective mineralocorticoid receptor antagonist (nsMRA) targeting MR and renin-angiotensin-aldosterone system (RAAS) overactivation. MR overactivation contributes to chronic kidney disease (CKD) progression and cardiovascular damage which can be driven by metabolic, hemodynamic, as well as inflammatory and fibrotic factors.

Finerenone was well-tolerated in the FINE-ONE study, which is consistent with the well-established safety profile of finerenone. No new safety signals were identified. The overall incidence of treatment-emergent serious adverse events was comparable between finerenone and placebo groups. Hyperkalemia-related adverse events occurred more frequently with finerenone than placebo (in 12 patients or 10.1% in the finerenone arm, versus in 4 patients or 3.3% in the placebo arm, respectively). There were no fatal adverse events of hyperkalemia in either treatment group, and the rate of hospitalization or discontinuation due to hyperkalemia was low.

Bayer plans to provide the data to health authorities for regulatory assessment of finerenone for the treatment of CKD associated with T1D in due course.

About Kerendia™ / Firialta™ (finerenone)
Kerendia™ and Firialta™ are globally protected trademarks for finerenone. Finerenone is a non-steroidal, selective mineralocorticoid receptor (MR) antagonist 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.

Finerenone is marketed as Kerendia™ or, in some countries, as Firialta™, and approved for the treatment of adult patients with CKD associated with type 2 diabetes (T2D) in more than 95 countries worldwide, including in China, Europe, Japan, and the U.S. Finerenone is also approved for the treatment of heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in the U.S.

The clinical study program with finerenone, FINEOVATE, currently comprises ten Phase III studies with dedicated programs in HF and CKD respectively. The MOONRAKER program includes the completed pivotal Phase III study FINEARTS-HF, as well as the ongoing collaborative, investigator-sponsored studies REDEFINE-HF, CONFIRMATION-HF, and FINALITY-HF. The THUNDERBALL CKD program consists of the completed Phase III studies FIDELIO-DKD, FIGARO-DKD, and FINE-ONE, and the Phase II study CONFIDENCE; as well as the ongoing Phase III studies FIND-CKD, FIONA, and FIONA-OLE.

About FINE-ONE
In FINE-ONE, 242 participants were randomized from more than 80 sites across 9 countries worldwide to receive either finerenone or placebo once daily. In addition, patients in the study received usual therapy to treat symptoms and comorbidities.

In FINE-ONE, finerenone significantly reduced the primary endpoint of relative change in UACR by 25% (percentage reduction, least squares geometric mean (LSGM) ratio 0.75 [95% CI, 0.65-0.87; p=0.0001]) from baseline over 6 months versus placebo. At any time post-baseline, 81 out of 119 participants (68.1%) in the finerenone arm, versus 54 out of 116 (46.6%) participants in the placebo arm achieved at least a 30% reduction in UACR, a threshold established by the American Diabetes Association (ADA) as being associated

with slower CKD progression in patients with CKD associated with type 2 diabetes. The safety profile of finerenone in FINE-ONE was consistent with previous studies and no new safety signals were identified.

FINE-ONE is a global, randomized, placebo-controlled, double-blind, multicenter Phase III study in people with CKD and T1D. The primary objective was to demonstrate whether the addition of finerenone to standard of care is superior to placebo in reducing UACR from baseline over six months. Secondary endpoints included the number of participants with treatment emergent adverse events and hyperkalemia (adverse event of special interest).

Participants were randomly assigned 1:1 to finerenone (10 or 20 mg OD) or a finerenone-matched placebo. The starting dose depended on estimated glomerular filtration rate (eGFR) level (10 mg for eGFR ≥25–<60 mL/min/1.73 m^2; 20 mg for eGFR ≥60 mL/min/1.73 m^2. Finerenone was uptitrated to the 20 mg target dose after 30 days if the serum/plasma [K+] is ≤4.8 mmol/L and the eGFR decrease is <30% compared with the value measured at the prior visit. Safety was assessed at all scheduled visits, including serum potassium determined both centrally and locally. Blood pressure was assessed at screening and all follow-up visits. UACR was assessed at screening, baseline, month 3, month 6 and at the follow-up visit one month post treatment.

About Chronic Kidney Disease associated with Type 1 Diabetes

Type 1 Diabetes (T1D) is a chronic autoimmune disorder characterized by destruction of pancreatic beta cells leading to insulin deficiency and requiring lifelong insulin treatment. Among the US population overall, crude estimates for 2018 indicated that 1.4 million adults aged 20 years or older (or 5.2% of all US adults with diagnosed diabetes), reported both having T1D and using insulin.

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. CKD is one of the most frequent complications arising from diabetes and is also an independent risk factor of cardiovascular disease.

CKD affects 30% of people with T1D. In a systematic analysis for the Global Burden of Disease study, it was reported that the prevalence of CKD associated with T1D had

increased by 58.2% from 1990 to 2007 and by 21.7% from 2007 to 2017. The 2017 global prevalence of CKD due to T1D was an estimated 32.5 per 100,000 individuals.

The clinical course of CKD in people with T1D is characterized by an increased urinary albumin excretion rate, which is a first sign of kidney damage and may progress to macroalbuminuria and decrease in kidney function as measured by estimated glomerular filtration rate (eGFR). The treatment of T1D consists of insulin treatment to control hyperglycemia. In people with T1D, blood glucose intervention targeting HbA1c levels ≤7% can slow onset and progression of kidney disease. Despite guideline-recommended treatment with ACEIs and ARBs, residual risk remains high in people with CKD and T1D, with up to a quarter progressing to end-stage-kidney-disease. CKD associated with T1D significantly increases the risk of cardiovascular events and kidney failure, contributing to CKD being a leading cause of death in T1D.

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 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 2024, the Group employed

around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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