CLOSER LOOK

MEMORANDUM

Kerendia (finerenone) receives FDA approval for adults with CKD associated with T1D – high tolerability and "Januvia-like" ease of use highlighted - September 17, 2026

FDA approval establishes Kerendia as the first new treatment in over 30 years for CKD associated with T1D; approval based on uACR reductions shown in the phase 3 FINE-ONE study (n=242)

Bayer announced today that the FDA has approved non-steroidal mineralcorticoid receptor antagonist (nsMRA) Kerendia (finerenone) for adults with T1D and chronic kidney disease (CKD) following Priority Review designation in May 2026 – this was a fast approval! This approval is based on the compelling phase 3 FINE-ONE study (n=242) reported at American Society of Nephrology and supported by findings from the phase 3 FIDELIO-DKD (n=5,734) and FIGARO-DKD (n=7,354) trials, which reflected finerenone studies in people with T2D. In FINE-ONE, finerenone reduced uACR (urine albumin-to-creatinine ratio, its primary endpoint) by 25% compared to placebo across three and six months in people with T1D and CKD. Full results were published in *NEJM* March 2026 by Professor Hiddo Heerspink et al. in "Finerenone in Type 1 Diabetes and Chronic Kidney Disease."

In the US, 20%-30% of people with T1D also have CKD – representing a high population that faces an elevated risk of kidney disease progression and kidney failure. As background, finerenone received FDA approval in July 2021 for the treatment of CKD associated with T2D based on FIDELIO-DKD results – which were first presented at ASN 2020. In July 2025, the FDA approved finerenone for people with heart failure with mid-range ejection fraction (HFmrEF) or preserved ejection fraction (HFpEF) based on the FINE-ARTS-HF trial (n=6,001) presented at ESC 2024. While a number of people with T1D did get Kerendia, clinicians were forced to use it off-label or not at all – reimbursement is far more likely with an official label.

With today's approval, once-daily oral finerenone is the first nsMRA indicated for adults with CKD associated with T1D. We are thrilled that people with T1D will likely receive far more education about kidney health – we think the numbers of people with T1D who are familiar with kidney health measures remains low but this could be a major catalyst for greater knowledge. Bayer will continue to pursue adjacent indications for Kerendia in CKD without diabetes and pediatric CKD with proteinuria.

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Finerenone conferred sustained, significant reductions in uACR in phase 3 FINE-ONE study

In its press release, Bayer noted that today's approval was supported primarily by results from the phase 3 FINE-ONE trial in adults with CKD and T1D, with additional support from FIDELIO-DKD and FIGARO-DKD – which studied finerenone in CKD associated with T2D. Notably, the T1D indication relies on uACR reduction as indicative of longer-term kidney benefit. Evidence from FIDELIO-DKD and FIGARO-DKD was used to connect reductions in uACR to improved kidney outcomes.

- **In phase 3 FINE-ONE study,** adults with CKD and T1D were randomized to receive once-daily finerenone (10 mg or 20 mg) or placebo on top of the standard of care. Finerenone conferred a 22% reduction in uACR compared to placebo at three months, and a 28% greater reduction at six months. Safety and tolerability were generally consistent with finerenone's established profile in CKD and T2D. Treatment-emergent adverse events occurred in 47% of participants receiving finerenone, compared to 49% receiving placebo. Notably,

patients taking finerenone reported an increased incidence of hyperkalemia (10.1%) compared to placebo (3.3%).

- **In the phase 3 FIDELIO-DKD study (n=5,734),** finerenone demonstrated an 18% relative risk reduction in the trial's primary composite kidney endpoint. Beyond the primary endpoint, finerenone conferred a 13% relative risk reduction for kidney failure and a 19% relative risk reduction in sustained eGFR decline greater than or equal to 40%.
- **In the phase 3 FIGARO-DKD study (n=7,354),** finerenone's addition to standard of care was found to significantly reduce the time to first non-fatal cardiovascular (CV) event or risk of CV-related death compared to placebo.

FDA indication for T1D and CKD features narrower language than July 2021's T2D and CKD approval

Notably, because finerenone's T1D-associated CKD indication was supported by albuminuria reduction in the FINE-ONE program, its wording is narrower than finerenone's established T2D-associated CKD indication. Specifically, finerenone is now approved to reduce uACR in adults with CKD associated with T1D – a reduction that is expected to lower the risk of sustained eGFR decline and end-stage kidney disease. The T1D-associated CKD indication does not reflect directly demonstrated long-term composite kidney outcomes in this population.

uACR is a modifiable factor associated with CKD progression

While finerenone was approved for CKD associated with T2D in July 2021, its original pivotal program – FIDELIO-DKD and FIGARO-DKD – was intentionally designed and powered for adults with T2D-associated CKD. Therefore, although finerenone's biologic mechanism and T2D clinical results provided a strong scientific rationale to investigate the therapy in T1D-associated CKD, they could not be automatically extrapolated to this population. The five-year interval between approvals was required to generate T1D-specific evidence through the FINE-ONE program, including data on albuminuria reduction and safety in this distinct population.

In the T2D program, finerenone-associated reductions in uACR were linked to improved kidney outcomes. Together, with the positive uACR findings from FINE-ONE, these results provide the basis for linking finerenone's established kidney-outcomes evidence in T2D to adults with CKD associated with T1D.

Close Concerns' Questions

1. Does Bayer plan to study finerenone in pediatric patients with T1D and CKD, given the long lifetime risk of kidney complications in this population?
2. Which adults with T1D and CKD are expected to benefit most from finerenone, and at what stage of CKD should clinicians consider initiating treatment?
3. How high is awareness about uACR and eGFR among people with T1D ?

-- by Caroline Metz, Elizabeth Rose, Riya Chatterjee, and Kelly Close