CLOSER LOOK

MEMORANDUM

FDA grants Priority Review to Bayer's Kerendia for the treatment of kidney disease with T1D – May 21, 2026

Supplemental New Drug Application supported by phase 3 FINE-ONE trial results in which Kerendia achieved a 25% reduction in uACR

Germany-based Bayer announced today that the FDA has accepted and granted Priority Review to its supplemental New Drug Application (sNDA) for Kerendia (finerenone) for a new indication in adults with T1D and chronic kidney disease (CKD). The sNDA was supported by the phase 3 FINE-ONE trial (n=242), which Bayer highlighted as the first phase 3 study since the 1990s to show positive results for patients with T1D and CKD. If approved, Kerendia would become the first mineralocorticoid receptor antagonist (MRA) indicated for T1D-associated CKD. Even though 20-30% of people in the US with T1D also have CKD, there are currently no approved therapies for CKD in people with T1D.

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Results from the FINE-ONE trial demonstrated significant reductions in uACR

The FINE-ONE trial enrolled adults from 82 centers across nine countries (Canada, China, Denmark, Germany, Italy, South Korea, Spain, UK, and US) with long-standing T1D and CKD and randomized them to finerenone or placebo. The study met its primary endpoint with finerenone producing a 25% reduction in urine albumin-to-creatinine ratio (uACR) over six months compared with placebo (least-squares mean ratio 0.75; 95% CI 0.64-0.87). This effect was consistent across age and sex subgroups.

Safety was comparable between groups, with similar rates of treatment-emergent and serious adverse events. Hyperkalemia occurred more frequently with finerenone (10.1% versus 3.3%) but had low clinical impact, with few cases leading to treatment discontinuation. Safety and tolerability were consistent with the efficacy evidence for people with T2D and CKD in the FIDELIO-DKD and FIGARO-DKD.

Kerendia's current FDA-approved indications include CKD and HF

Kerendia is already approved in the US for CKD associated with T2D, where it is indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and heart-failure (HF) hospitalization. As of July 2025, the therapy is also FDA-approved to reduce cardiovascular death, heart-failure hospitalization, and urgent emergency visits in adults with HF with LVEF ≥40%. Subsequently, the therapy was approved for the same indication in Japan, Korea, Thailand, and Taiwan in 4Q25. Kerendia's potential expansion into T1D and CKD would build on its rapidly growing cardio-renal portfolio, which also includes positive topline results from the FIND-CKD study (n=1,584) in adults with non-diabetic CKD and multiple ongoing phase 3 HF trials within the MOONRAKER program.

Development continues on Kerendia for T1D following strong results presented at ASN 2026

We were fortunate to attend the American Society of Nephrology's annual meeting in 2025. During the opening plenary, Prof. Hiddo Heerspink (University of Groningen, the Netherlands) presented full results for FINE-ONE. He said that in

the US, roughly 27% of people with T1D have CKD, and prevalence increases with age – around 35% of people with T1D aged 40+ also have CKD, and this figure increases to 55% by age 60+ and 79% by age 80+.

The positive study findings were met with applause from the packed conference hall. Indeed, the potential impact of this study is great, as people with T1D and CKD have been limited to two treatment options for over three decades.

Kerendia's global sales continued to grow in 1Q26

Kerendia continues to experience strong momentum in 1Q26, with sales reaching $274 million, up 70% from 1Q25, but down 10% sequentially. Year-over-year growth was driven primarily by volume growth in the US and China. In the Bayer's 1Q26 report, management stressed that the sequential decline is a result of comparison with a particularly strong 4Q25. Bayer projects 50% full-year net sales growth in 2026, underscoring its confidence in sustained uptake across the CKD and HF indications.

Close Concerns' Questions

1. What evidence thresholds might committees require to consider finerenone for earlier intervention in the progression of CKD with T1D?
2. How might Bayer's marketing evolve to clearly differentiate Kerendia's new indication?
3. How might this new indication (if approved) increase overall brand visibility and also boost awareness among people with T2D?

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