CLOSER LOOK

MEMORANDUM

Bayer's Kerendia (finerenone) receives FDA approval for heart failure – July 14, 2025

First in class nsMRA to receive approval for heart failure; follows Priority Review Designation in March 2025 and phase 3 FINEARTS-HF trial results

Bayer announced today that the FDA has approved non-steroidal mineralocorticoid receptor antagonist (nsMRA) Kerendia (finerenone) for people with heart failure with mid-range ejection fraction (HFmrEF) or preserved ejection fraction (HFpEF)[1], following Priority Review Designation in March 2025. This approval is based on the results from the phase 3 FINEARTS-HF trial (n=6,001) presented at ESC 2024 and published in *NEJM*, in which finerenone demonstrated a 16% relative risk reduction of the primary composite outcome of total heart failure events and cardiovascular death over just 32 months among people with HFmrEF or HFpEF.

Today's news expands finerenone's indication for adults with CKD associated with T2D. With an expanded treatment option for HFmrEF and HFpEF, finerenone has the potential to impact 3.7 million adults in the US who are at high risk of hospitalization for heart failure and cardiovascular death. We'll continue to closely follow, especially as Bayer announced plans in 1Q25 to launch finerenone for heart failure in 2025 and awaits decisions in China, the EU, and Japan.

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Approval based on the phase 3 FINEART-HF trial conducted across 635 sites in 37 countries

Today's approval is based on the results from the phase 3 FINEARTS-HF trial (n=6,001), which included people with HFmrEF or HFpEF across 635 sites in 37 countries. The primary outcome was a composite of total worsening heart failure events and death from cardiovascular causes. The secondary outcomes included the following: (i) total worsening heart failure events; (ii) change from baseline in the total symptom score on the KCCQ at six, nine, and 12 months; (iii) improvement in the New York Heart Association (NYHA) functional class at 12 months; and (iv) kidney composite outcome.

Over 32 months, finerenone demonstrated a 16% relative risk reduction of the primary composite outcome of total heart failure events and cardiovascular death. All-cause mortality was lower in the finerenone group (HR 0.93). Furthermore, the mean change from baseline in the KCCQ total symptom score across months six, nine, and 12 was 8.0 points in the finerenone group and 6.4 in the placebo group (higher scores are healthier). Improvement in the NYHA functional class at 12 months was observed in 19% of the finerenone group and 18% in the placebo group. A kidney composite outcome event occurred in 2.5% of patients in the finerenone group and 1.8% in the placebo group. Benefits of finerenone were consistent across all prespecified subgroups, including those with or without the use of SGLT-2 inhibitors. The safety profile of finerenone was consistent across all indications.

Finerenone expands indications beyond CKD and T2D; ongoing trial in T1D

Since its approval in July 2021 for adults with CKD associated with T2D, finerenone has demonstrated impressive growth. In 1Q25, finerenone sales totaled $169 million, up 87% from 1Q24 and up 18% sequentially. With broad utilization in CKD and T2D, finerenone has also shown strong penetration in OUS regions like China, India, and Mexico. Bayer continues to study finerenone in three additional phase 3 trials in the MOONRAKER program: (i) REDEFINE-HF (n=5,200) on early, in-hospital initiation of finerenone; (ii) CONFIRMATION-HF (n=1,500) on combination therapy of finerenone and SGLT-2 inhibitors; and (iii) FINALITY-HF (n=2,600) on finerenone in people

with HFrEF who cannot tolerate steroidal MRAs.

Finerenone is also being studied in people with CKD and T1D in the phase 3 FINE-ONE trial (n=220). According to ClinicalTrials.gov, the trial is expected to complete in September 2025, which is a little earlier than the previously expected October 2025. If successful, finerenone may potentially help fulfill significant needs, as treatment options for CKD and T1D have remained unchanged for over a decade.

Close Concerns' Questions

1. What is Bayer's updated timeline for launching Kerendia for heart failure in the US?
2. When does Bayer expect decisions for Kerendia's expanded indication in China, the EU, and Japan?
3. How does Bayer plan to increase education and awareness among patients and HCPs about the impact Kerendia could have on patient outcomes?

--by Esther Min, Monica Oxenreiter, and Kelly Close

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[1] HFmrEF is defined as heart failure with left ventricular ejection fraction (LVEF) <40%. HFpEF is defined as heart failure with LVEF ≥50%.