CLOSER LOOK

MEMORANDUM

NEJM publishes full phase 3 FINE-ONE trial results, demonstrating renal benefits of finerenone in people with T1D and CKD – March 5, 2026

Finerenone led to 25% greater reduction in uACR than placebo at six months; follows trial readout at ASN Kidney Week 2025

NEJM just published full results of the phase 3 FINE-ONE trial, titled "Finerenone in Type 1 Diabetes and Chronic Kidney Disease," by Prof. Hiddo Heerspink (University of Groningen, the Netherlands) et al. The FINE-ONE study (n=242) evaluated finerenone, a nonsteroidal mineralocorticoid receptor antagonist, in people with T1D and chronic kidney disease (CKD). At six months, finerenone conferred 25% greater reduction in urinary albumin-to-creatinine ratio (uACR) compared to placebo from a severely elevated baseline of over 500 mg/g (as background, normal range is <30 mg/g). These benefits were consistent across subgroups based on baseline eGFR, uACR, and demographic characteristics, which were:

- Mean age and diabetes duration of ~52 years old and 32 years, respectively;
- Mean eGFR of 59 mL/min/1.73 m2, indicating mild to moderately decreased kidney function; and
- Median UACR of 575 and 506 mg/g for the finerenone and placebo groups, respectively, indicating severely increased levels of albumin in urine.

While participants on finerenone and placebo still reported high uACR of 374 mg/g and 476 mg/g after treatment, respectively, finerenone is the first adjunct-to-insulin therapy in 30 years to demonstrate positive results in addressing CKD in T1D. Overall, the safety profile was comparable to placebo. Most common adverse events included hyperkalemia – high potassium level – and reduction in eGFR by 5.6 mg/min/1.73 m^2 (vs. 2.7 mg/min/1.73 m^2) from a mildly low baseline of 59 mg/min/1.73 m^2. Though hyperkalemia incidence was significantly in the finerenone group (10.1%; 12 participants) compared to placebo (3.3%; four participants), Prof. Heerspink previously emphasized that its clinical impact was low. Both hyperkalemia and reduction in eGFR returned to baseline after treatment discontinuation. See more in our coverage of the trial readout at the American Society of Nephrology.

--by Kat Moon, Elizabeth Rose, Monica Oxenreiter, and Kelly Close