

# Interim Results from FINE-REAL: A Prospective Study Providing Insights into the Use of Finerenone in Routine Clinical Settings

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## Introduction

- Finerenone, a selective non-steroidal mineralocorticoid receptor antagonist (MRA), is approved for the treatment of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) worldwide, including the European Union, United States, China, and Japan.<sup>1,2</sup>
- Finerenone is included as a recommended treatment for CKD associated with T2D in guidance from the American Diabetes Association, American Association of Clinical Endocrinologists, European Society of Cardiology, and the Kidney Disease Improving Global Outcomes (KDIGO) work group.<sup>3-6</sup>
- The FINE-REAL study (NCT05348733) aims to evaluate the characteristics and treatment patterns of participants with CKD associated with T2D, who were enrolled across many countries and treated with finerenone in routine clinical practice. An interim analysis of FINE-REAL with a median 7 months' follow-up observation (initiation of finerenone treatment to last recorded observation) is presented.

## Methods

- Eligible participants were aged ≥18 years with a diagnosis of CKD associated with T2D based on physician assessment.<sup>7</sup>
- Participants were receiving finerenone (10 or 20 mg) in accordance with the local marketing authorization.
- The primary endpoint was to describe clinical characteristics and treatment patterns in participants with CKD and T2D treated with finerenone.
- Secondary endpoints were the occurrence of treatment emergent adverse events (TEAEs) and serious TEAEs, particularly hyperkalemia.
- The data cutoff for this interim analysis was June 13, 2023.

## Results

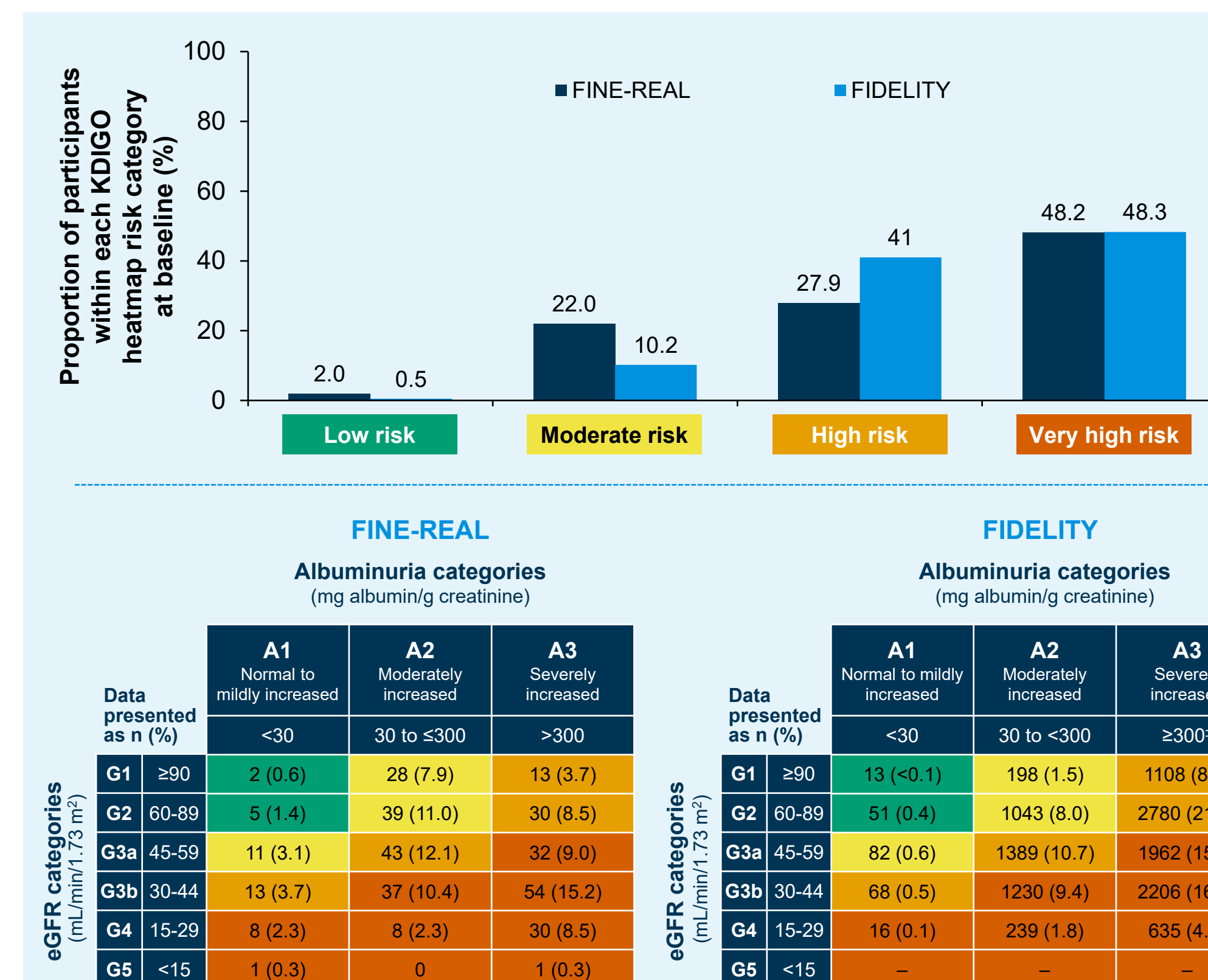
- Of 556 participants enrolled in the study at the cutoff date, 504 were included in the full analysis set. Eleven participants did not meet all inclusion criteria or met an exclusion criterion, four withdrew their consent, and one was excluded due to medical reasons. Another 35 participants had not yet started their finerenone treatment by the cutoff date.
- Baseline demographics and disease characteristics, including estimated glomerular filtration rate (eGFR), urine albumin:creatinine ratio (UACR), and prior/concomitant therapies are shown in **Table 1**.
- The proportions of participants in the low-risk, moderate-risk, high-risk, and very high-risk KDIGO risk categories in FINE-REAL and FIDELITY (a pooled analysis of patients with CKD and T2D from the phase 3 FIDELIO-DKD and FIGARO-DKD studies)<sup>8</sup> are shown in **Figure 1**.
- At the cutoff date, participants in the full analysis set had been followed for a median (interquartile range [IQR]) of 211.5 (104.0-301.5) days.
- A total of 443 (87.9%) participants were prescribed finerenone 10 mg and 61 (12.1%) participants were prescribed finerenone 20 mg at the cutoff date.
- After initiation of finerenone, treatment was defined as either continuously administered, interrupted, or withdrawn in 465 (92.3%), 27 (5.4%), and five (1.0%) participants, respectively (per participant evaluation at the last available visit).

**Table 1. Baseline demographics and disease characteristics†**

Characteristic	All participants (N=504)
<b>Age</b> , mean (SD), years	66.1 (11.0)
<b>Sex</b> , n (%)	
Male	306 (60.7)
Female	198 (39.3)
<b>Race or ethnic group</b> , n (%)	
White	269 (53.4)
Asian	112 (22.2)
Black/African American	65 (12.9)
Other/not reported‡	58 (11.5)
<b>Duration of T2D</b> , median (IQR), years	14.0 (8.0-22.0)
<b>History of heart failure</b> , n (%)	67 (13.3)
<b>UACR</b> , median (IQR), mg/g,§	295.0 (85.9-897.0)
<b>UACR category</b> , n (%)	
<30	40 (8.0)
30 to <300	143 (28.6)
≥300	176 (35.2)
<b>eGFR</b> , mean (SD), mL/min/1.73 m <sup>2</sup> ,	52.0 (24.3)
<b>eGFR category</b> , n (%)	
<15	3 (0.6)
15-29	72 (14.7)
30-44	154 (31.4)
45-59	119 (24.3)
60-89	93 (19.0)
≥90	49 (10.0)
<b>Serum potassium</b> , mean (SD), mmol/L	4.4 (0.4)
<b>HbA1c</b> , mean (SD), %	7.5 (1.5)
<b>Systolic blood pressure</b> , mean (SD), mmHg	138.0 (18.7)
<b>Prior/concomitant medication</b> , n (%)	
Statins	387 (76.8)
ACEi/ARB	362 (71.8)
Insulin	241 (47.8)
SGLT2 inhibitor	235 (46.6)
GLP-1 receptor agonist	168 (33.3)

†Baseline demographics and disease characteristics are captured from medical records or by interviewing the participant. Clinical variables of interest are shaded green. ‡American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, and not reported. §71.23% of participants had UACR measurements at baseline. ¶Calculated using the CKD-EPI 2009 formula without adjustment for race. ¶7.22% of participants had eGFR measurements at baseline. ¶ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; eGFR, estimated glomerular filtration rate; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; GLP-1, glucagon-like peptide-1; HbA1c, glycated hemoglobin; IQR, interquartile range; SD, standard deviation; SGLT2, sodium-glucose cotransporter 2; T2D, type 2 diabetes; UACR, urine albumin:creatinine ratio.

**Figure 1. Proportion according to KDIGO heatmap CKD risk categories in FINE-REAL and FIDELITY at baseline†,§**



†Pooled analysis of patients with CKD and T2D from the phase 3 FIDELIO-DKD and FIGARO-DKD studies. ‡Only participants with a UACR with an upper limit of ≤5000 mg/g were permitted into the FIDELIO DKD or FIGARO DKD studies. CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; KDIGO, Kidney Disease Improving Global Outcomes; T2D, type 2 diabetes; UACR, urine albumin:creatinine ratio.

- Safety information is shown in **Table 2**.

**Table 2. Summary of TEAEs overall**

Event, n (%)	Participants (N=504)
<b>Any TEAE</b>	110 (21.8)
<b>Any serious TEAE</b>	27 (5.4)
<b>Any TEAE with fatal outcome</b>	1 (0.2)

TEAE, treatment-emergent adverse event.

- TEAEs were reported in 112 participants (22.2%). The three most frequently reported TEAEs were hyperkalemia/blood potassium-increased (25 participants; 5.0%), urinary tract infection (6 participants; 1.2%), and vitamin D deficiency (6 participants; 1.2%).
- Serious TEAEs were reported in 27 participants (5.4%). The three most frequently reported serious TEAEs were acute kidney injury (5 participants; 1.0%), coronary artery disease (2 participants; 0.4%), and urinary tract infections (2 participants; 0.4%).
- One patient with concomitant hepatic cancer died during the study because of hepatic failure.

- Information on hyperkalemia TEAEs is shown in **Table 3**.

**Table 3. Number (percentage) of participants with hyperkalemia† TEAEs**

Outcome, n (%)	All participants (N=504)
<b>Any event</b>	25 (5.0)
<b>Symptomatic event</b>	1 (0.2)
<b>Clinical signs/symptoms (multiple answers possible)</b>	
Paresthesia	1 (0.2)
<b>Leading to dialysis</b>	0
<b>Leading to hospitalization</b>	0
<b>Serum potassium &gt;5.5 mmol/L</b>	21 (4.2)
<b>Serum potassium &gt;6.0 mmol/L</b>	2 (0.4)

†The term hyperkalemia refers to the combined MedDRA PTs hyperkalemia and blood potassium increased. MedDRA, Medical Dictionary for Regulatory Activities; PT, preferred term; TEAE, treatment-emergent adverse event.

## Conclusions

- FINE-REAL is the first global prospective observational study investigating the use of a non-steroidal MRA in routine clinical care in patients with CKD and T2D.
- At baseline, most participants were classified as very high risk per the KDIGO CKD risk categories, >70% of participants were prescribed an ACEi/ARB, and 48% of participants were prescribed a SGLT2 inhibitor.
- Relative to FIDELITY,<sup>8</sup> at the time of this interim analysis, FINE-REAL included a greater proportion of participants in the moderate KDIGO risk category, fewer participants in the high-risk category, and a similar number of participants in the very high-risk category.
- This interim analysis showed that the occurrence of hyperkalemia in the real-world setting was low, with no fatal hyperkalemia and no hyperkalemia leading to dialysis or hospitalization.
- Results from FINE-REAL will help to inform decision-making with respect to initiation of finerenone in patients with CKD and T2D.
- Future analyses should provide insights into the dynamics of new therapy adoption across different geographies.

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