Dosing, treatment patterns, UACR changes, and safety with finerenone treatment: An interim analysis of the Asian cohort of FINE-REAL

Poster number: P360

Nan Hee Kim[1], Lixin Guo[2], Kevin M. Pantalone[3], Christoph Wanner[4], David C. Wheeler[5], Nihar R. Desai[6], Ricardo Correa-Rotter[7], Susanne B. Nicholas[8], Sonia Ares Goméz[9], Andrea Horvat-Broecker[10], Marcel Schulz[11], Martin Merz[11], Sankar D. Navaneethan[12]

[1]Division of Endocrinology and Metabolism, Department of Internal Medicine, Korea University College of Medicine, Seoul, South Korea; [2]Department of Endocrinology, Beijing Hospital, National Center of Gerontology, Institute of Geriatric Medicine, Chinese Academy of Medical Sciences, Beijing, China; [3]Cleveland Clinic, Cleveland, OH, USA; [4]University Hospital Würzburg, Würzburg, Germany; [5]University College London, London, UK; [6]Yale School of Medicine, New Haven, CT, USA; [7]Instituto Nacional de Ciencias Médicas y Nutricion Salvador Zubiran, Ciudad de Mexico, Mexico; [8]David Geffen School of Medicine, University of California, Los Angeles, CA, USA; [9]Syneos Health, Madrid, Spain; [10]Bayer AG, Wuppertal, Germany; [11]Bayer AG, Berlin, German; [12]Baylor College of Medicine, Houston, TX, USA.

Introduction

- Finerenone is a guideline-directed, selective non-steroidal mineralocorticoid receptor antagonist, approved for the treatment of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) worldwide.[1,2]
- FINE-REAL (NCT05348733) assesses real-world finerenone use in participants aged ≥ 18 years with a physician diagnosis of CKD associated with T2D.
- This interim analysis describes dosing strategies, treatment patterns, UACR changes, and safety during treatment with finerenone in the FINE-REAL Asian cohort.

Methods

- FINE-REAL is a global, prospective, single-arm, non-interventional study conducted in 19 countries.
- Participants were only enrolled after the decision to initiate finerenone.
- Participants received finerenone 10 or 20 mg once daily in accordance with the local marketing authorization.
- Primary endpoint: to describe clinical characteristics and treatment pattern in participants with CKD and T2D treated with finerenone.
- Secondary endpoints: occurrence of treatment-emergent adverse events (TEAEs), serious TEAEs, and hyperkalemia during finerenone therapy, regardless of any potential relationship to treatment.
- Data were collected between June 13, 2022 and June 13, 2025.

Results

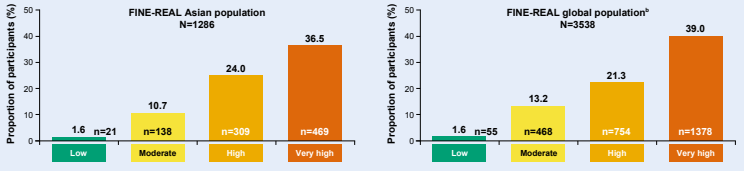
- 1286 Asian participants were enrolled from China mainland (n=297; 23%), South Korea (n=716; 56%), Singapore (n=21; 2%), Taiwan (n=177; 14%), and Thailand (n=75; 6%), mainly across nephrology (n=652; 51%) and endocrinology (n=605; 47%) departments.
- Median (IQR) follow-up time was 120 (1–337) days versus 268 (113–366) in the global population.
- Finerenone was initiated at 10 mg in 984 (77%) and 20 mg in 302 (24%) participants.
- In the Asian cohort, 173/984 (18%) participants initiated on 10 mg were up-titrated at least once and 25/302 (8%) participants initiated on 20 mg were down-titrated at least once.
- Baseline mean (SD) eGFR was 55 (21) mL/min/1.73 m^2 (n=1255) and median (IQR) UACR was 515 (198–1292) mg/g (n=943), versus 53 (22) mL/min/1.73 m^2 (n=3440) and 334 (106–911) mg/g (n=2680), respectively, in the global population.
- UACR declined between baseline and 4 months and 12 months, with reductions from baseline in median UACR of 41% and 42%, respectively (**Table 2**).

Table 1. Baseline demographics and disease characteristics[a]

Characteristic	FAS (N=1286)
Age, mean (SD), years	66 (12)
Male, n (%)	897 (70)
Duration of T2D, mean (SD), years (n=1148)	16 (10)
Duration of CKD, mean (SD), years (n=1111)	5 (5)
UACR, median (IQR), mg/g (n=943)	515 (198–1292)
eGFR, mean (SD), mL/min/1.73 m^2 (n=1255)[b]	55 (21)
Serum potassium, median (IQR), mmol/L (n=1208)	4 (4–5)
HbA1c, mean (SD), % (n=1014)	8 (2)
Systolic blood pressure, mean (SD), mmHg (n=1173)	136 (18)

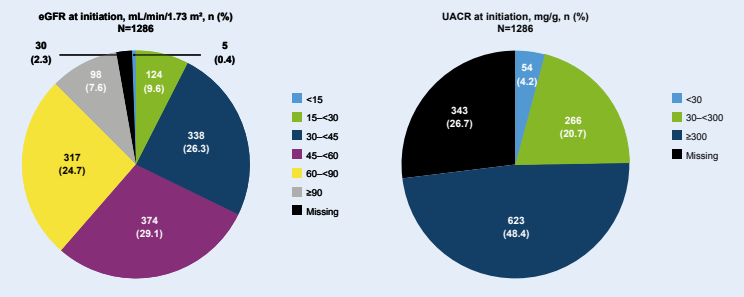
[a]Captured from medical records or by interviewing the participant. Clinical variables of interest are shaded green. [b]Calculated using the CKD-EPI 2009 formula without adjustment for race. CKD, chronic kidney disease; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; eGFR, estimated glomerular filtration rate; FAS, full analysis set; HbA1c, glycated hemoglobin; IQR, interquartile range; SD, standard deviation; T2D, type 2 diabetes; UACR, urine albumin:creatinine ratio.

Figure 1. KDIGO[a] risk categories in the FINE-REAL Asian and global populations



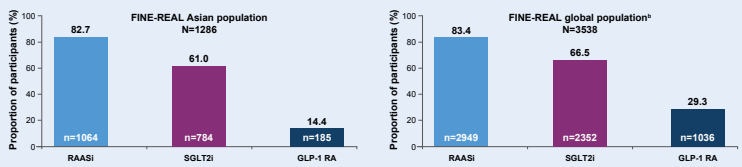
[a]KDIGO risk category was unknown in 349 (27.1%) participants in the FINE-REAL Asian population and 883 (25.0%) in the FINE-REAL global population. [b]Global population includes the Asian cohort. KDIGO, Kidney Disease: Improving Global Outcomes.

Figure 2. eGFR and UACR at finerenone initiation



eGFR data are CKD-EPI without race (calculated). CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; eGFR, estimated glomerular filtration rate; UACR, urine albumin:creatinine ratio.

Figure 3. Prior/concomitant medication[a] at finerenone initiation in the FINE-REAL Asian and global populations



[a]Medication started prior to and still ongoing at finerenone initiation. [b]Global population includes the Asian cohort.
GLP-1 RA, glucagon-like peptide-1 receptor agonist; RAASi, renin–angiotensin-aldosterone system inhibitor; SGLT2i, sodium–glucose cotransporter 2 inhibitor.

Table 2. UACR changes (N=1286)

	Baseline	4 months	12 months
Number of participants	1286	711	209
N (%) with UACR data	943 (73)	349 (49)	159 (76)
Median UACR (IQR), mg/g	515 (198–1292)	303 (112–804)	299 (86–643)
Relative change from BL in median UACR[a], %	—	−41	−42
Median relative change from BL[b], % (95% CI)	—	−32 (−43, −28)	−33 (−43, −26)
<30 mg/g, n (%)	54 (6)	31 (9)	18 (11)
30–<300 mg/g, n (%)	266 (28)	142 (41)	62 (39)
≥300 mg/g, n (%)	623 (66)	176 (50)	79 (50)

Analysis only included participants with an available UACR value at BL through 12 months. Timepoints were defined as the last value prior to initiation of finerenone (BL), 32 to 152 days (4 months), and 275 to 395 days (12 months). Participants who were still in the study but had not reached their 12-month visit were not included.
[a]% change from BL median value to follow-up median value. [b]Median of % changes for each participant.
BL, baseline; CI, confidence interval; IQR, interquartile range; UACR, urine albumin:creatinine ratio.

Table 3. Summary of safety data[a]

n (%) participants experiencing TEAEs	FAS (N=1286)
Any TEAE[b]	379 (29)
Most common TEAEs (≥1%)	
Hyperkalemia[c,d]	104 (8)
Urinary tract infection[c]	34 (3)
Hematuria[e]	15 (1)
Study drug-related TEAEs	122 (9)
TEAEs leading to permanent study drug discontinuation	14 (1)
TEAEs leading to death	6 (<1)
Any serious TEAE[f]	110 (9)
Study drug-related serious TEAEs	7 (<1)
Serious TEAEs leading to permanent discontinuation of study drug	5 (<1)
Serious TEAEs leading to hospitalization	104 (8)

[a]By MGL, SOC, and PT. [b]By SOC. [c]By MGL. [d]Including PTs "hyperkalemia" and "blood potassium increased"; reported by the investigator. [e]SubMGL of "urogenital tract hemorrhage" and included PTs "hematuria" and "red blood cells urine positive"; reported by the investigator. [f]No serious TEAEs occurred in ≥1% of participants.
FAS, full analysis set; MGL, MedDRA group labeling; PT, preferred term; SOC, system organ class; TEAE, treatment-emergent adverse event.

Table 4. Treatment-emergent hyperkalemia[a,b]

n (%) participants experiencing events of hyperkalemia	FAS (N=1286)
TEAE of hyperkalemia	104 (8)
Study drug-related	80 (6)
Leading to permanent study drug discontinuation	5 (<1)
Serious TEAE of hyperkalemia	2 (<1)
Study drug-related	2 (<1)
Leading to hospitalization	1 (<1)

[a]By MGL, SOC, and PT. [b]By MGL; included PTs "hyperkalemia" and "blood potassium increased"; reported by the investigator. No events of hyperkalemia led to dialysis, were life-threatening, or led to death.
FAS, full analysis set; MGL, MedDRA group labeling; PT, preferred term; SOC, system organ class; TEAE, treatment-emergent adverse event.

Conclusions

- Kidney impairment by UACR at baseline in the Asian cohort of FINE-REAL was more severe compared with the global population.
- The distribution of participants in CKD risk categories according to KDIGO in the Asian cohort was similar to the global population.
- RAASi and SGLT2i use was similar in the Asian cohort and global population, but GLP-1 RA use was greater in the global population. RAASi, SGLT2i, and GLP-1 RA use was greater in both populations than in recent registries.[3–5]
- In addition to other guideline-directed therapies in many participants, finerenone reduced UACR between baseline and 4 months; this effect was maintained at 12 months.
- Safety was favorable and consistent with the known safety profile of finerenone.

References
1. Bayer HealthCare Pharmaceuticals Inc. KERENDIA (finerenone) tablets, for oral use: US prescribing information. Available at: https://labeling.bayerhealthcare.com/html/products/pi/Kerendia_PI.pdf. Accessed Dec 22, 2025.
2. Bayer HealthCare Pharmaceuticals Inc. Kerendia summary of product characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/kerendia-epar-product-information_en.pdf. Accessed Dec 22, 2025.
3. Nicholas SB, et al. Diabetes Obes Metab 2023;25:2970–9.
4. Lim C-E, et al. Eur J Prev Cardiol 2023;30:634–43.
5. Jeong SJ, et al. BMC Nephrol 2021;22:177.

Acknowledgments
The authors would like to thank the participants, their families, and all investigators involved in this study. Medical writing support, under the guidance of the authors, was provided by Laura Chalmers, PhD, an employee from the Publications and Medical Affairs Division of Omnicom Health Medical Communications and was funded by Bayer AG in accordance with Good Publication Practice, GPP 2022 (Ann Intern Med 2022;175:1298–1304).

Contact: Prof. Nan Hee Kim; Email: nhkendo@gmail.com