# Dosing, treatment patterns, UACR changes, and safety with finerenone treatment in routine care: FINE-REAL interim analysis

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FINE-REAL

# Disclosures

Dr. Correa Rotter discloses:

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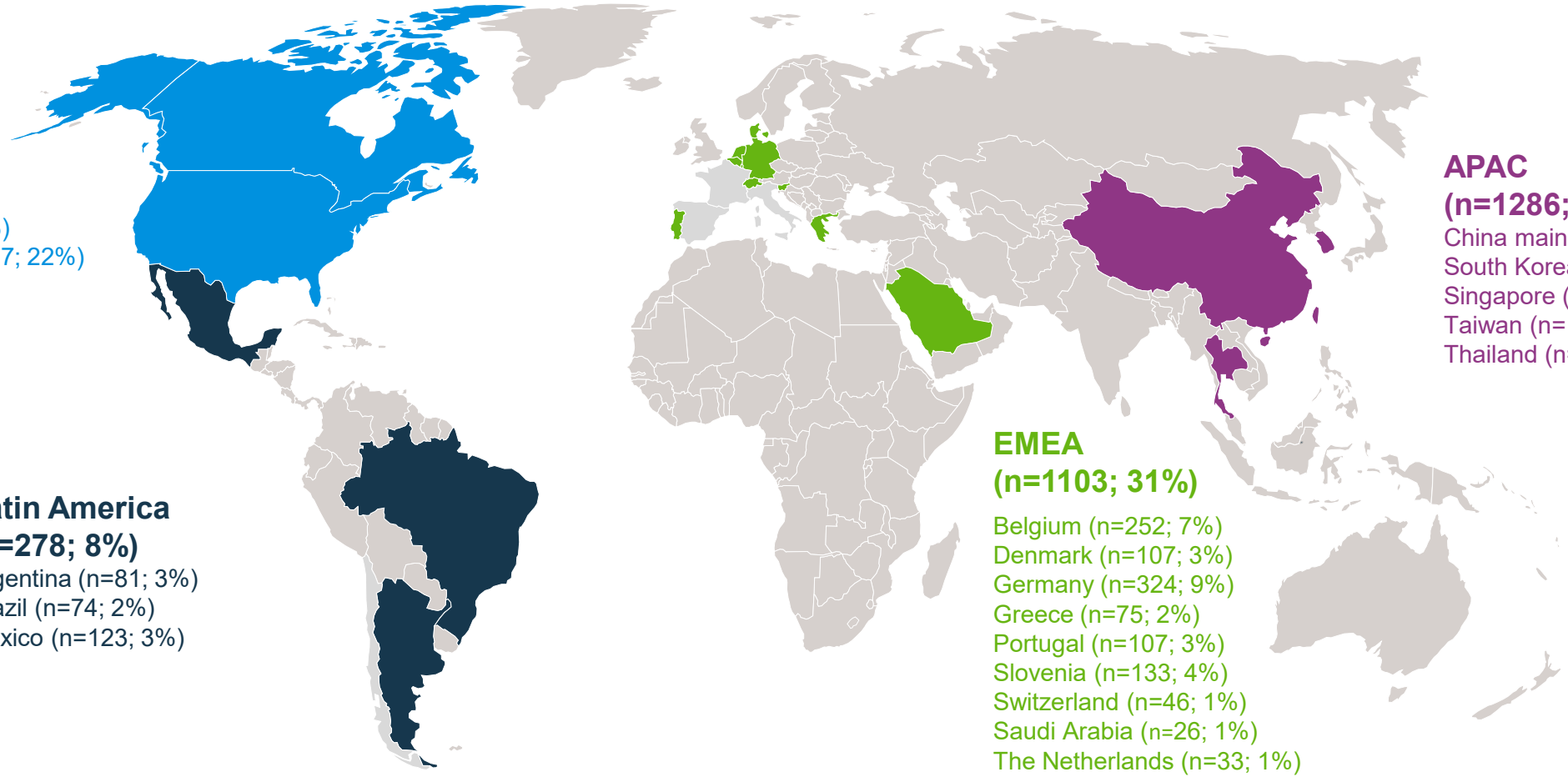
# Background/Methods

- The non-steroidal mineralocorticoid receptor antagonist finerenone is approved for the treatment of CKD associated with T2D[1,2]
- FINE-REAL (NCT05348733) is the first global, prospective, observational study on the use of finerenone (10 or 20 mg) in participants (aged ≥18 years) with CKD and T2D in routine clinical practice[3]
- This pre-planned interim analysis describes data collected from June 13, 2022, to June 13, 2025 (data cutoff)
- Assessments included demographics, dosing strategies/treatment patterns, concomitant medications, UACR changes, laboratory parameters, and TEAEs with a focus on hyperkalemia

1. Bayer Inc. Kerendia US PI 2025: Available at https://labeling.bayerhealthcare.com/html/products/pi/Kerendia_PI.pdf. 2. Bayer Inc. Kerendia EU SmPC 2022: Available at https://www.ema.europa.eu/en/documents/product-information/kerendia-epar-product-information_en.pdf. 3. Desai NR, et al. J Diabetes Complications 2023;37:108411.
CKD, chronic kidney disease; T2D, type 2 diabetes; TEAE, treatment-emergent adverse event; UACR, urine albumin:creatinine ratio.

# FINE-REAL included participants from 19 countries



**North America**
**(n=871; 25%)**
Canada (n=104; 3%)
United States (n=767; 22%)

**Latin America**
**(n=278; 8%)**
Argentina (n=81; 3%)
Brazil (n=74; 2%)
Mexico (n=123; 3%)

**EMEA**
**(n=1103; 31%)**
Belgium (n=252; 7%)
Denmark (n=107; 3%)
Germany (n=324; 9%)
Greece (n=75; 2%)
Portugal (n=107; 3%)
Slovenia (n=133; 4%)
Switzerland (n=46; 1%)
Saudi Arabia (n=26; 1%)
The Netherlands (n=33; 1%)

**APAC**
**(n=1286; 36%)**
China mainland (n=297; 8%)
South Korea (n=716; 20%)
Singapore (n=21; 1%)
Taiwan (n=177; 5%)
Thailand (n=75; 2%)

APAC, Asia Pacific; EMEA, Europe, Middle East, and Africa.

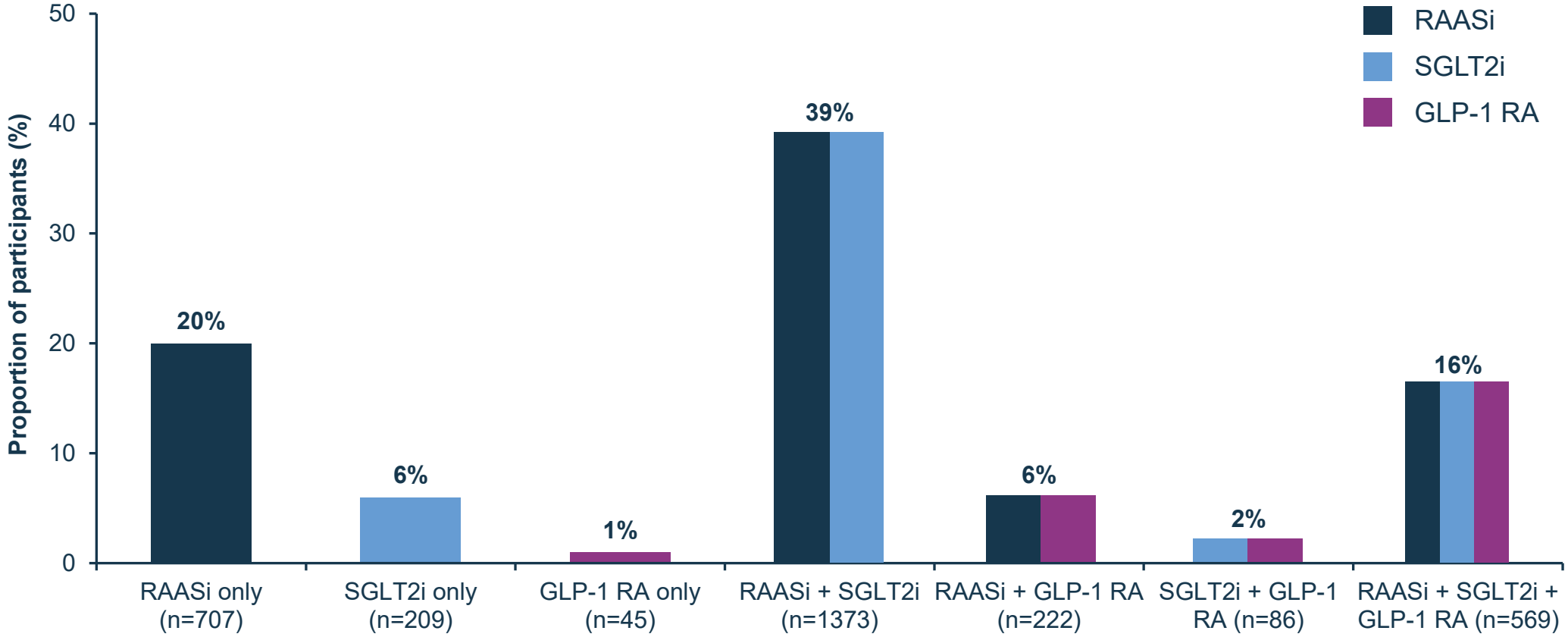
# Baseline demographics and disease characteristics

| | N=3538 |
|---|---|
| Age, mean (SD) | 67.4 (11.1) |
| Sex, n (%) | |
| Male | 2363 (67) |
| Female | 1175 (33) |
| BMI, median (IQR), kg/m$^2$ (n=2725) | 28.7 (25.2, 33.1) |
| UACR, median (IQR), mg/g (n=2680) | 334.4 (105.7, 910.7) |
| eGFR,[a] mean (SD), mL/min/1.73 m$^2$ (n=3440) | 52.7 (22.1) |
| Serum potassium, median (IQR), mmol/L (n=3331) | 4.5 (4.1, 4.7) |

- Median follow-up was 268 days

[a]Calculated using The Chronic Kidney Disease Epidemiology Collaboration 2009 formula (CKD-EPI) without adjustment for race.
BMI, body mass index; eGFR, estimated glomerular filtration rate; IQR, interquartile range; SD, standard deviation; UACR, urine albumin:creatinine ratio.

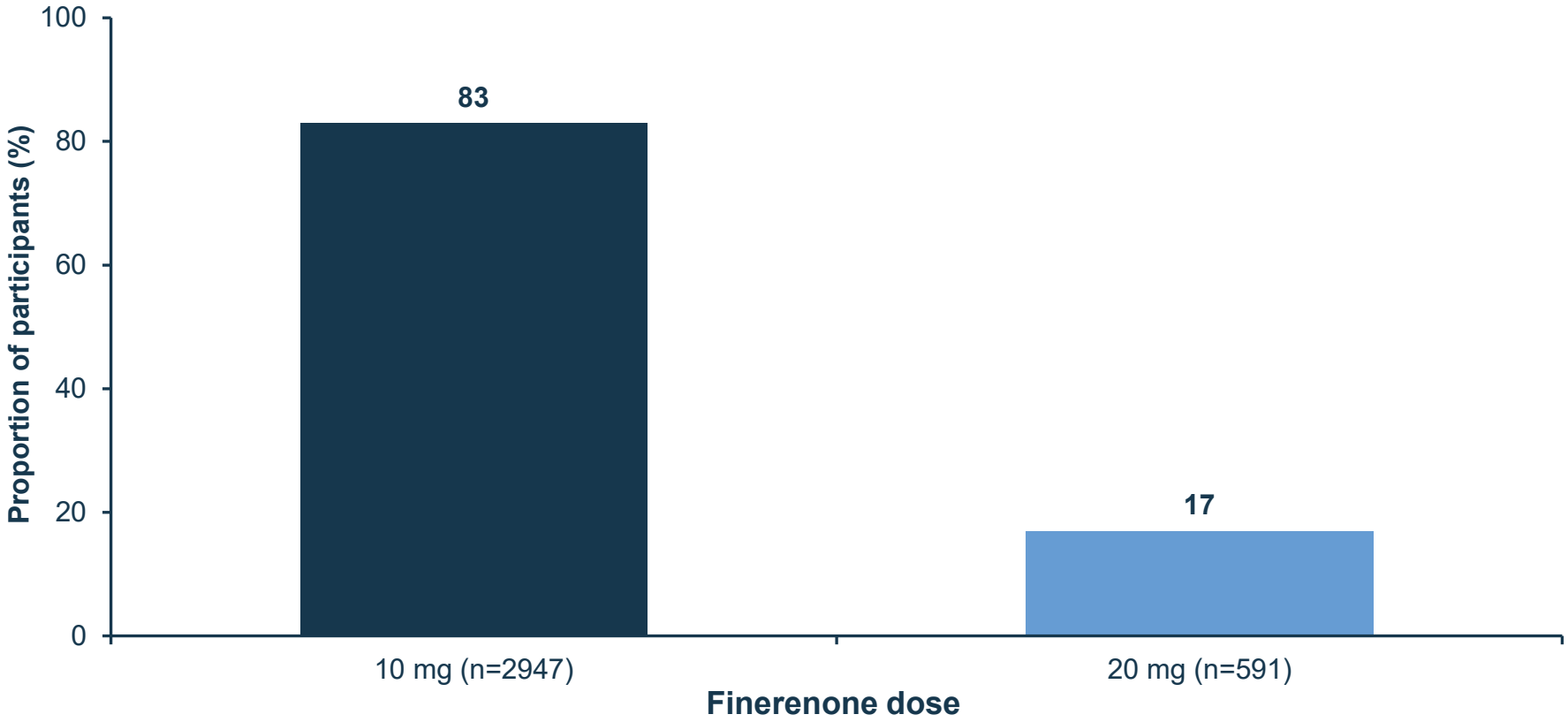
# RAAS inhibitors and SGLT2 inhibitors were the most common concomitant medications




- RAASi, SGLT2i, and GLP-1 RA were received by 2949 (83%), 2352 (66%), and 1036 (29%) participants, respectively

GLP-1 RA, glucagon-like peptide-1 receptor agonist; RAASi, renin-angiotensin-aldosterone system inhibitor; SGLT2i, sodium-glucose cotransporter-2 inhibitor.

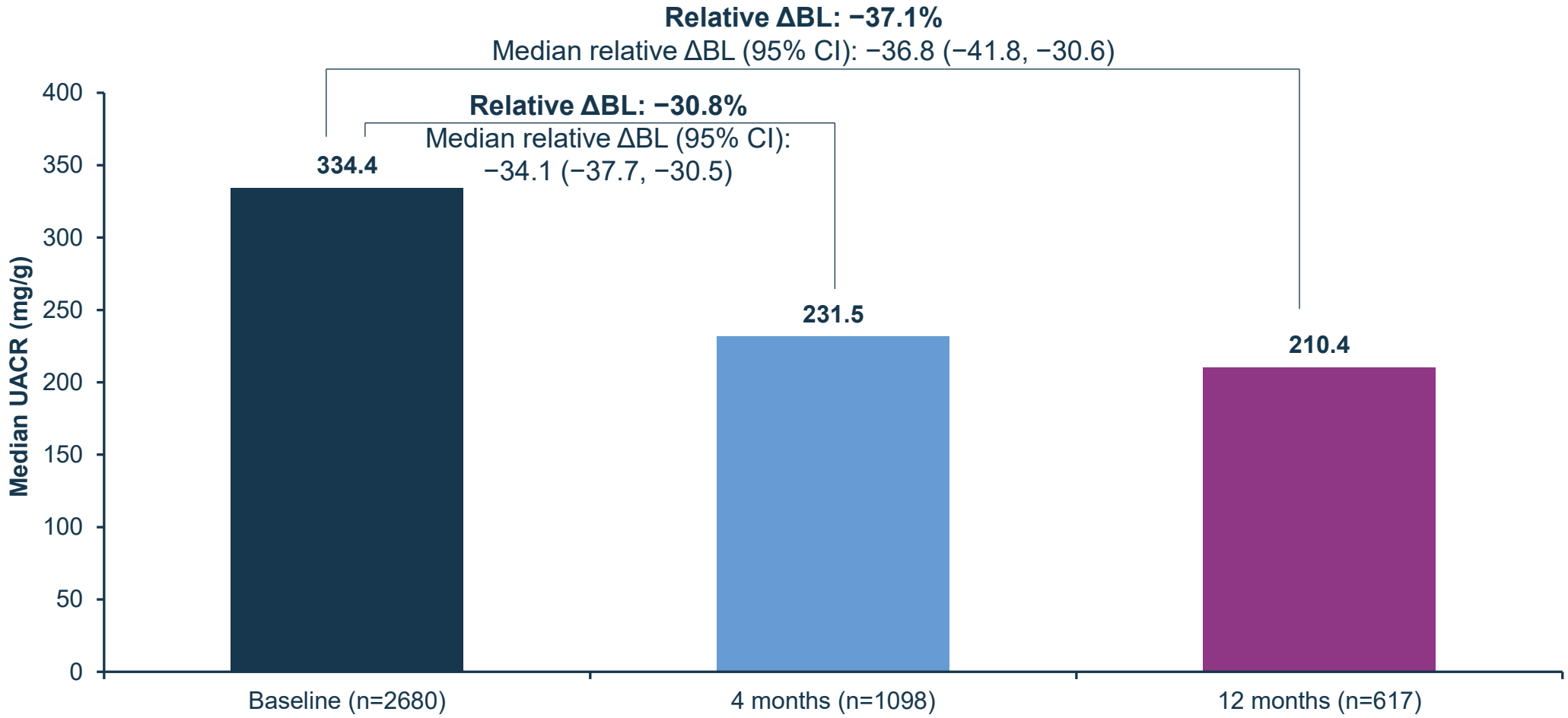
# Finerenone 10 mg was most commonly used at initiation




- Of 991 participants with eGFR ≥60 mL/min/$m^2$ who were eligible for 20 mg per label, 566 (57%) were initiated on 10 mg
- At 12 months, 617 (55%) and 498 (44%) participants were on 10 mg and 20 mg, respectively

eGFR, estimated glomerular filtration rate.

# Median UACR declined over time with finerenone use




- A >30% reduction in UACR was observed between BL and 4 months with an additional, smaller reduction between 4 and 12 months
- At 4 months and 12 months, respectively, 54% (n=590/1098) and 55% (n=340/617) participants had ≥30% UACR reduction from BL

Data shown are for participants with UACR values at BL and at 4/12 months.
ΔBL, change from baseline; CI, confidence interval; UACR, urine albumin:creatinine ratio.

# Treatment-emergent adverse events and serious treatment-emergent adverse events

| | n (%)<br>N=3538 |
|---|---|
| Any TEAE | 1388 (39.2) |
| TEAE (>1.0%), n (%) | |
| Hyperkalemia[a] | 300 (8.5) |
| Urinary tract infection | 143 (4.0) |
| Urinary tract hemorrhage[b] | 84 (2.4) |
| Renal failure | 52 (1.5) |
| Diarrhea | 45 (1.3) |
| Dizziness | 37 (1.1) |

| | n (%)<br>N=3538 |
|---|---|
| Any serious TEAE, n (%) | 408 (11.5) |
| Serious TEAE (>0.5%), n (%) | |
| Acute kidney injury | 26 (0.7) |
| Hyperkalemia[a] | 23 (0.7) |

TEAEs were any adverse events that happened during finerenone therapy regardless of any potential relationship to treatment.
[a]Including hyperkalemia and blood potassium increased; reported at the discretion of the investigator. [b]Including hematuria (n=79; 2.2%).
TEAE, treatment-emergent adverse event.

# Conclusions

- By UACR and eGFR, participants in FINE-REAL had less advanced CKD versus FIDELIO-DKD[1]
- Use of concomitant RAASi, SGLT2i, or GLP-1 RA was higher in FINE-REAL than in typical real-world practice[2–4]
- Most participants (83%) were initiated on finerenone 10 mg
- 57% (n=566) of participants with eGFR ≥60 mL/min/$m^2$ initiated on finerenone 10 mg rather than the recommended 20 mg
- Despite concomitant RAASi, SGLT2i, or GLP-1 RA in many participants, UACR declined from BL by 31% and 37% at 4 months and 12 months, respectively, exceeding ADA recommendations[5] despite finerenone being initiated at lower doses than indicated in many cases
- At 4 months and 12 months, respectively, 54% (n=590/1098) and 55% (n=340/617) of participants had ≥30% UACR reduction from BL
- Safety was consistent with the known safety profile of finerenone[6,7]

1. Bakris GL, et al. N Engl J Med 2020;383:2219–29. 2. Nicholas SB, et al. Diabetes Obes Metab 2023;25:2970–9. 3. Lim C-E, et al. Eur J Prev Cardiol 2023;30:634–43. 4 Jeong SJ, et al. BMC Nephrol 2021;22:177. 5. ADA Professional Practice Committee. Diabetes Care 2025;48:S239–51. 6. Agarwal R, et al. Eur Heart J 2022;43:474–84. 7. Pitt B, et al. N Engl J Med 2021;385:2252–63.
ADA, American Diabetes Association; BL, baseline; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; GLP-1 RA, glucagon-like peptide-1 receptor agonist; RAASi, renin-angiotensin-aldosterone system inhibitor; SGLT2i, sodium-glucose cotransporter-2 inhibitor; UACR, urine albumin:creatinine ratio.

# Back-up slides

# Race and ethnicity

| | n (%); N=3538 |
|---|---|
| Race | |
| White | 1560 (44) |
| Black/African American | 196 (6) |
| Asian | 1411 (40) |
| American Indian/Alaska Native | 20 (1) |
| Native Hawaiian/Other Pacific Islander | 6 (<1) |
| Not reported | 344 (10) |
| Missing | 1 (<1) |
| Ethnicity | |
| Not Hispanic or Latino | 2715 (77) |
| Hispanic or Latino | 415 (12) |
| Not reported | 407 (12) |
| Missing | 1 (<1) |

Percentages may not add up to 100 due to rounding.

# UACR declined over time with finerenone use

| N=3538 | BL | 4 months | 12 months |
|---|---|---|---|
| Total participants at each timepoint (N) | 3538 | 2738 | 1717 |
| n (%) with UACR data at BL and 4/12 months | 2680 (76) | 1098 (40) | 617 (36) |
| Median (IQR), mg/g | 334.4 (105.7, 910.7) | 231.5 (67.5, 687.0) | 210.4 (55.0, 637.0) |
| <30 mg/g, n (%) | 200 (7) | 155 (14) | 94 (15) |
| 30 to <300 mg/g, n (%) | 1035 (39) | 465 (42) | 265 (43) |
| ≥300 mg/g, n (%) | 1445 (54) | 478 (44) | 258 (42) |

- UACR should be monitored regularly as the ADA recommends a reduction of >30% from BL or to <300 mg/g[1]
- At BL, 24% of participants did not have a UACR value
- At 4 months and 12 months, respectively, 60% and 64% of participants did not have a UACR value at BL and follow-up

1. ADA Professional Practice Committee. Diabetes Care 2025;48:S239–51.
ADA, American Diabetes Association; BL, baseline; IQR, interquartile range; UACR, urine albumin:creatinine ratio.

# Course of UACR in participants with UACR data available at BL and 4 months or BL and 12 months: Sensitivity analysis

| N=3538 | BL | 4 months | BL | 12 months |
|---|---|---|---|---|
| n (%) | 1098 | 1098 | 617 | 617 |
| Median (IQR), mg/g | 382.10 (123.00, 1012.00) | 231.50 (67.48, 687.00) | 346.02 (114.00, 859.00) | 210.43 (55.00, 637.00) |
| Relative change from BL in median UACR, % | | −39.41 | | −39.18 |
| Median relative change from BL (95% CI) | | −34.07 (−37.65, −30.52) | | −36.84 (−41.84, −30.59) |
| <30 mg/g, n (%) | 65 (6) | 155 (14) | 41 (7) | 94 (15) |
| 30 to <300 mg/g, n (%) | 411 (37) | 465 (42) | 240 (39) | 265 (43) |
| ≥300 mg/g, n (%) | 622 (57) | 478 (44) | 336 (54) | 258 (42) |

n (%) refers to the number of participants with UACR data available at BL and 4 months or BL and 12 months. Relative change from BL in median UACR represents the percentage change in median UACR when comparing median UACR at BL and median UACR at Month 4/12 (estimated from aggregated data). Median relative change from BL represents the median percentage change in UACR from BL across all participants with UACR recorded at BL and Month 4/12 (estimated from individual participant data).
BL, baseline; IQR, interquartile range; UACR, urine albumin:creatinine ratio.

# Hyperkalemia events were serious in <1% of participants and none led to dialysis or death

| | n (%)<br>N=3538 |
|---|---|
| Any hyperkalemia[a] event | 300 (8) |
| Study drug-related | 246 (7) |
| Leading to permanent discontinuation | 35 (1) |
| Serious hyperkalemia[a] events | 23 (1) |
| Study drug-related | 21 (1) |
| Leading to permanent discontinuation | 5 (<1) |
| Leading to hospitalization | 9 (<1) |

[a]Including hyperkalemia and blood potassium increased; reported at the discretion of the investigator.