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Finerenone in patients with chronic kidney disease and type 1 diabetes according to geographic region: A FINE-ONE analysis

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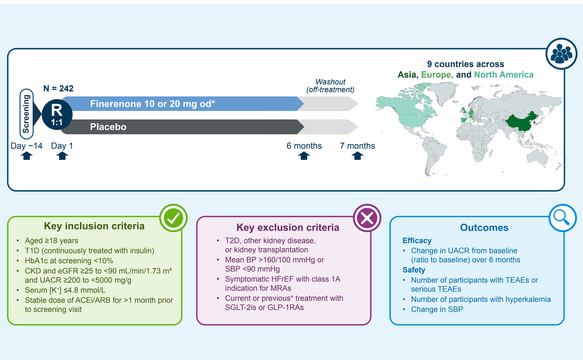
Background

- Chronic kidney disease (CKD) develops in approximately one-third of people with type 1 diabetes (T1D),[1] and the proportion of individuals affected increases with diabetes duration[2]
- The incidence and prevalence associated with CKD and T1D have increased worldwide since 1990, although the disease burden varies across global regions, with high prevalences in Europe and North America, and high disability in parts of Asia[3]
- The risks associated with CKD in people with T1D include cardiovascular (CV) disease, CKD progression, and kidney failure[4]
  - Although international guidelines recommend therapies to control blood glucose and reduce blood pressure in this population,[5] no novel therapies are available to help mitigate kidney and CV risks
- Finerenone, a nonsteroidal mineralocorticoid receptor antagonist, was shown to improve kidney and CV outcomes in people with CKD and type 2 diabetes[6]
- In the global FINE-ONE trial (NCT05901831) assessing people with CKD and T1D, finerenone versus placebo significantly reduced albuminuria by 25% over 6 months of treatment and was well-tolerated[7]
- This post hoc analysis of FINE-ONE aimed to assess the efficacy and safety of finerenone among participants in the trial enrolled in different geographical regions

Methods

- The FINE-ONE global, placebo-controlled, double-blind, phase III study randomized participants 1:1 to oral finerenone (10 mg or 20 mg) or matching placebo[8]
- The study design, inclusion and exclusion criteria, and outcomes for FINE-ONE are shown in **Figure 1**
  - Included were adults with T1D (glycated hemoglobin levels <10% [<86 mmol/mol]) and CKD (estimated glomerular filtration rate [eGFR] of 25 to 90 mL/min/1.73 m^2 and urinary albumin-to-creatinine ratio [UACR] of 200 to <5000 mg/g) who had serum potassium concentration ≤4.8 mmol/L and were on a stable dose of a renin–angiotensin system inhibitor for ≥4 weeks before screening
  - Participants were enrolled from sites in three regions: Asia (China, South Korea), Europe (Denmark, Germany, Italy, Spain, United Kingdom), and North America (Canada, United States)
  - The primary efficacy outcome was the relative change in UACR from baseline over 6 months
  - Treatment-emergent adverse events (AEs), hyperkalemia, and changes in systolic blood pressure were also assessed

Figure 1. FINE-ONE study design



*≤8 weeks prior to screening
ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BP, blood pressure; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; GLP-1RA, glucagon-like peptide-1 receptor agonist; HbA1c, glycated hemoglobin; HFrEF, heart failure with reduced ejection fraction; [K⁺], potassium concentration; MRA, mineralocorticoid receptor antagonist; R, randomization; SBP, systolic blood pressure; SGLT-2i, sodium-glucose co-transporter-2 inhibitor; T1D, type 1 diabetes; T2D, type 2 diabetes; TEAE, treatment-emergent adverse event; UACR, urinary albumin-to-creatinine ratio

Statistical analysis

- Efficacy outcomes were split according to region and were performed in the full analysis set, which included all randomized participants; the safety analysis set included all randomized participants who took at least one dose of study drug
- The primary efficacy analysis was performed using a mixed-effects model for repeated measures, including treatment, log-transformed baseline value, study visit, region, log-transformed baseline-by-visit interaction, treatment-by-visit interaction, treatment group-by-region interaction, visit-by-region interaction, and treatment-by-region-by-visit interaction

Results

Participants

- FINE-ONE included 242 participants, of whom 39 (16.1%) were in Asia, 120 (49.6%) were in Europe, and 83 (34.3%) were in North America (**Table 1**)
  - All participants in Asia were Asian
  - In Europe, 111 (92.5%) participants were White
  - In North America, 64 (77.1%) were White and 12 (14.5%) were Black
- There were some differences between participants in different regions:
  - Participants in Asia had a shorter duration of diabetes, were younger (mean age of 46.3 years vs 52.9 years in Europe and 52.1 years in North America), and had a lower mean BMI (22.7 kg/m^2 vs 27.8 kg/m^2 and 29.5 kg/m^2, in Europe and North America, respectively)
    - Asian participants were also more likely to have a history of CV disease (41.0% vs 26.7% in Europe and 15.7% in North America)
  - Participants in Europe were more likely to be male (71.7% vs 59% in Asia and North America)
  - More participants in North America had an eGFR <45 mL/min/1.73 m^2 (38.6% vs 28.2% in Asia and 16.7% in Europe)

Table 1. Baseline demographic and clinical characteristics according to region

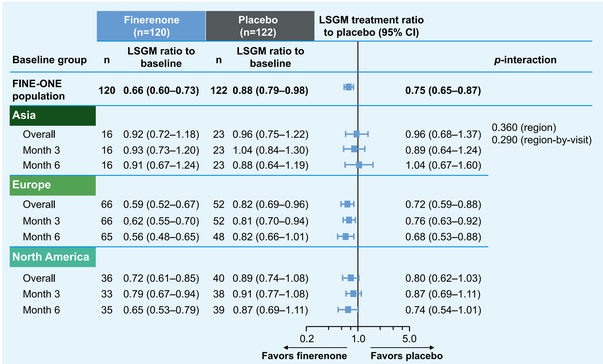
Characteristic	Asia (n=39)	Europe (n=120)	North America (n=83)	Overall (N=242)
Age, years, mean ± SD	46.3 ± 13.6	52.9 ± 13.2	52.1 ± 13.9	51.6 ± 13.7
Sex, male, n (%)	23 (59.0)	86 (71.7)	49 (59.0)	158 (65.3)
Race, n (%)				
White	0 (0)	111 (92.5)	64 (77.1)	175 (72.3)
Black	0 (0)	4 (3.3)	12 (14.5)	48 (19.8)
Asian	39 (100.0)	3 (2.5)	5 (6.0)	15 (6.2)
Other*	0 (0)	2 (1.7)	2 (2.4)	4 (1.7)
BMI,# kg/m^2, mean ± SD	22.7 ± 3.5	27.8 ± 4.9	29.5 ± 7.1	27.5 ± 6.0
Blood pressure, mmHg, mean ± SD				
Systolic	122.6 ± 16.8	139.9 ± 15.9	134.8 ± 15.0	135.4 ± 16.8
Diastolic	76.4 ± 9.4	79.4 ± 11.0	75.4 ± 10.8	77.6 ± 10.8
Biochemical measurements				
HbA1c,‡ %, mean ± SD	7.6 ± 1.0	7.7 ± 1.0	7.6 ± 1.1	7.6 ± 1.1
UACR,§ mg/g, median (Q1–Q3)	484.4 (284.6–1647.8)	558.7 (305.9–1247.8)	511.2 (289.8–958.0)	549.0 (297.0–1209.5)
UACR category, mg/g, n (%)				
<300	12 (30.8)	29 (24.2)	23 (27.7)	64 (26.4)
300–1000	12 (30.8)	58 (48.3)	41 (49.4)	111 (45.9)
>1000	15 (38.5)	33 (27.5)	19 (22.9)	67 (27.7)
eGFR, mL/min/1.73 m^2, mean ± SD	59.7 ± 19.0	61.5 ± 17.5	54.7 ± 21.0	58.9 ± 19.2
eGFR category, mL/min/1.73 m^2, n (%)				
<45	11 (28.2)	20 (16.7)	32 (38.6)	63 (26.0)
45–<60	7 (17.9)	38 (31.7)	17 (20.5)	62 (25.6)
≥60	21 (53.8)	62 (51.7)	34 (41.0)	117 (48.3)
Serum [K⁺], mmol/L, mean ± SD	4.6 ± 0.4	4.6 ± 0.4	4.5 ± 0.4	4.6 ± 0.4
Medical history				
Duration of diabetes, years, mean ± SD	19.7 ± 10.8	34.2 ± 13.3	34.6 ± 13.9	32.0 ± 14.2
Age at diabetes onset, years, mean ± SD	27.1 ± 16.9	19.3 ± 12.8	17.9 ± 11.6	20.1 ± 13.5
History of CVD,¶ n (%)	16 (41.0)	32 (26.7)	13 (15.7)	61 (25.2)
History of hypertension, n (%)	30 (76.9)	103 (85.8)	74 (89.2)	207 (85.5)
Medication use, n/N (%)**				
ACEis	1 (2.6)	72 (60.0)	38 (45.8)	111/241 (46.1)
ARBs	37 (94.9)	46 (38.3)	45 (54.2)	128/241 (53.1)
Diuretics	7 (17.9)	46 (38.3)	19 (22.9)	88/241 (36.5)

*Race was not reported in two European participants; two North American participants were American Indian or Alaska Native; #BMI values missing for two European participants (one each in the finerenone and placebo groups); ‡HbA1c values missing for two North American participants in the placebo group; §presented as median; ¶history of CVD was determined by the presence of one of the following in the medical history: myocardial infarction, coronary artery stenosis, cerebrovascular accident, transient ischemic attack, peripheral arterial occlusive disease, or cardiac failure; **use of sodium–glucose cotransporter-2 inhibitors and glucagon-like peptide-1 receptor agonists was not permitted in FINE-ONE
ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; CVD, cardiovascular disease; eGFR, estimated glomerular filtration rate; HbA1c, glycated hemoglobin; [K⁺], potassium concentration; Q, quartile; SD, standard deviation; UACR, urinary albumin-to-creatinine ratio

Efficacy

- Median (Q1–Q3) UACR at baseline in the overall population was 549.0 mg/g (297.0–1209.5)
  - Median UACR at baseline was 484.4 mg/g (284.6–1647.8) in Asia, 558.7 mg/g (305.9–1247.8) in Europe, and 511.2 mg/g (289.8–958.0) in North America
- The effects of finerenone on UACR were not modified by region (*p*-interaction=0.360) or by region-by-visit (*p*-interaction=0.290) (**Figure 2**)

Figure 2. Change in UACR from baseline in regional subgroups according to visit



CI, confidence interval; LSGM, least squares geometric mean; UACR, urinary albumin-to-creatinine ratio

Safety

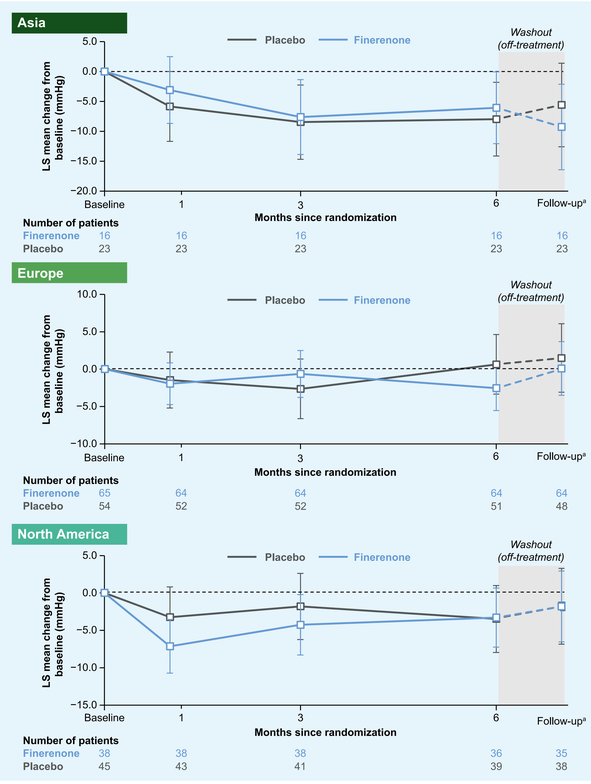
- Safety was generally balanced between treatment arms with no notable differences in the percentage of participants with treatment-emergent AEs or serious AEs across regions (**Table 2**)
  - There were three permanent discontinuations in participants receiving finerenone, with none in Asia
- Hyperkalemia was more common with finerenone than placebo across all regions
  - In Europe, incidences were 6.2% with finerenone and 1.9% with placebo, and the respective rates in North America were 10.5% and 2.2%
  - A greater proportion of participants in Asia versus other regions had hyperkalemia in both study arms; incidences were 4 (25%) with finerenone and 2 (8.7%) with placebo
- Differences in changes from baseline in systolic blood pressure between finerenone and placebo at 6 months were 1.91 mmHg (95% CI −6.50 to 10.31) among participants in Asia, −3.18 mmHg (95% CI −8.10 to 1.74) in Europe, and 0.18 mmHg (95% CI −5.76 to 6.12) in North America (**Figure 3**)

Table 2. Treatment-emergent AEs according to region

	Asia		Europe		North America	
	Finerenone (n=16)	Placebo (n=23)	Finerenone (n=65)	Placebo (n=54)	Finerenone (n=38)	Placebo (n=45)
Any treatment-emergent AE	9 (56.3)	12 (52.2)	29 (44.6)	29 (53.7)	18 (47.4)	19 (42.2)
Related to study drug	5 (31.3)	3 (13.0)	9 (13.8)	6 (11.1)	5 (13.2)	5 (11.1)
Leading to permanent discontinuation of study drug	0 (0)	0 (0)	2 (3.1)	2 (3.7)	1 (2.6)	1 (2.2)
Any treatment-emergent SAE	3 (18.8)	4 (17.4)	6 (9.2)	4 (7.4)	5 (13.2)	6 (13.3)
Related to study drug	0 (0)	0 (0)	2 (3.1)	0 (0)	1 (2.6)	0 (0)
Leading to permanent discontinuation of study drug	0 (0)	0 (0)	2 (3.1)	1 (1.9)	1 (2.6)	0 (0)
Leading to hospitalization	3 (18.8)	4 (17.4)	6 (9.2)	2 (3.7)	3 (7.9)	4 (8.9)
Leading to death	0 (0)	0 (0)	0 (0)	1 (1.9)	0 (0)	0 (0)
Any hyperkalemia*	4 (25.0)	2 (8.7)	4 (6.2)	1 (1.9)	4 (10.5)	1 (2.2)
Any serious hyperkalemia#	0 (0)	0 (0)	1 (1.5)	0 (0)	1 (2.6)	0 (0)

*Hyperkalemia includes investigator-reported AEs with MedDRA codes hyperkalemia and blood potassium increased; #there were no fatal hyperkalemia events
AE, adverse event; SAE, serious adverse event

Figure 3. Changes in SBP from baseline according to region



Error bars denote 95% CI
*30 days after last dose of study intervention with a ±7-day window permitted
LS, least squares; SBP, systolic blood pressure

Conclusions

- FINE-ONE enrolled a geographically diverse population with CKD and T1D
- Finerenone reduced UACR versus placebo over 6 months of treatment, irrespective of geographical region, with a consistent and tolerable safety profile

Acknowledgments

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