FIND-CKD

Design and Baseline Characteristics of the FIND-CKD Trial: Efficacy of Finerenone on Kidney Disease Progression in People with Non-Diabetic Chronic Kidney Disease (CKD)

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Disclosures

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FIGARO-DKD and FIDELIO-DKD: Background to FIND-CKD

FIND-CKD

Finerenone is associated with significant risk reductions in CV and kidney outcomes in participants with CKD **associated with T2D**[1] as shown in the **FIGARO-DKD and FIDELIO-DKD phase 3 studies**

Based on data from the phase 3 studies, finerenone is approved for the treatment of CKD **associated with T2D** worldwide, including the European Union, United States, China, and Japan[2,3]

Finerenone is included as a **recommended treatment** for CKD associated with T2D in guidance from the **ADA, AACE, ESC**, and the **KDIGO work group**[4–7]

FIND-CKD: First phase 3 trial of finerenone in patients with CKD **of non-diabetic etiology**

AACE, American Association of Clinical Endocrinologists; ADA, American Diabetes Association; CKD, chronic kidney disease; CV, cardiovascular; ESC, European Society of Cardiology; FIND-CKD, **FI**nerenone, in addition to standard of care, on the progression of kidney disease in patients with **N**on-**D**iabetic **C**hronic **K**idney **D**isease; T2D, type 2 diabetes; KDIGO, Kidney Disease Improving Global Outcomes.

1. Agarwal R, et al. *Eur Heart J* 2022;43:474-484. 2. Bayer HealthCare Pharmaceuticals Inc. KERENDIA (finerenone) tablets, for oral use: US prescribing information. 2021. https://labeling.bayerhealthcare.com/html/products/pi/Kerendia_PI.pdf. Accessed October 10, 2023; 3. Bayer HealthCare Pharmaceuticals Inc. Kerendia summary of product characteristics. 2022. https://www.ema.europa.eu/en/documents/product-information/kerendia-epar-product-information_en.pdf. Accessed October 10, 2023. 4. de Boer IH, et al. *Kidney Int*. 2022;102:974-989. 5. Blonde L, et al. *Endocr Pract*. 2022;28:923-1049. 6. Draznin B, et al. *Diabetes Care*. 2022;45:S175-S184. 7. Marx N, et al. *Eur Heart J*. 2023; ehad192. Presented at the American Society of Nephrology Kidney Week, Philadelphia, Pennsylvania, November 2-5, 2023.

Eligible Patients are Those With Non-Diabetic CKD on Optimized SoC Therapy With an ACEi or ARB

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Key inclusion criteria

Age ≥18 years

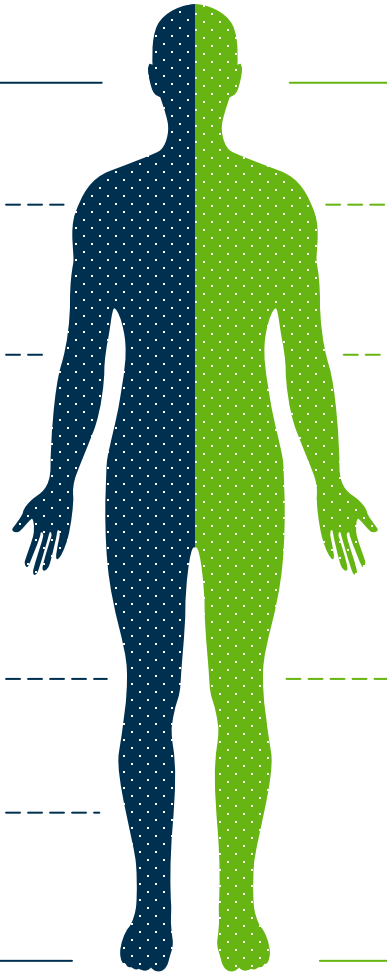
eGFR of ≥25 to <60 mL/min/1.73 m^2 and UACR of ≥200 to <500 mg/g†

OR

eGFR ≥25 to <90 mL/min/1.73 m^2 and UACR of ≥500 to ≤3500 mg/g

Serum potassium ≤4.8 mmol/L

On stable maximal tolerated labelled dose of ACEi or ARB



Key exclusion criteria

T1D, T2D, or HbA1c ≥6.5%

SBP ≥160 or DBP ≥100 mmHg

Symptomatic HF with reduced ejection fraction with class 1A indication for MRAs

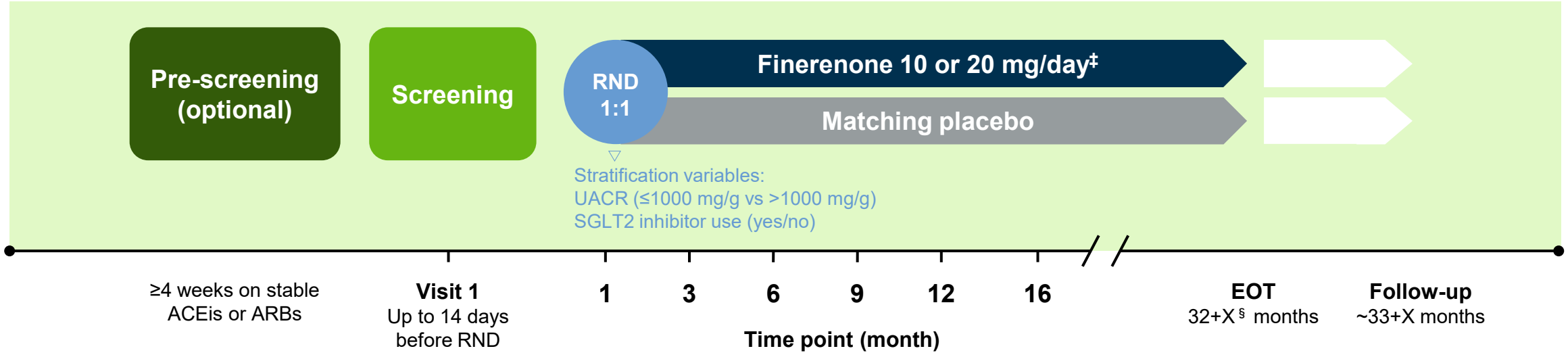
Autosomal dominant or autosomal recessive polycystic kidney disease

Lupus nephritis or ANCA-associated vasculitis or any other kidney disease requiring immunosuppressive therapy within 6 months prior to screening

†To ensure a pre-specified ratio for a population at risk of progressive renal function decline, the number of participants with eGFR of ≥25 to 60 mL/min/1.73 m^2 and UACR ≥200 to <500 mg/g is planned to be capped at approximately 10% of the total population.

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ANCA, anti-neutrophilic cytoplasmic autoantibody; CKD, chronic kidney disease; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; HbA1c, glycated hemoglobin; HF, heart failure; K^+, potassium; MRA, mineralocorticoid receptor antagonist; SBP, systolic blood pressure; SoC, standard of care; T1D, type 1 diabetes; T2D, type 2 diabetes; UACR, urinary albumin:creatinine ratio. Presented at the American Society of Nephrology Kidney Week, Philadelphia, Pennsylvania, November 2-5, 2023.

FIND-CKD is a Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 3 Study†



Primary endpoint

Total eGFR slope (defined as the mean annual rate of change in eGFR from baseline to Month 32)

Secondary endpoints

Composite of kidney failure, sustained eGFR decline of ≥57% from baseline, HHF, or CV death.
Composite of kidney failure or sustained eGFR decline of ≥57% from baseline.
Composite of HHF or CV death

Safety outcomes

Occurrence of treatment-emergent AEs, treatment-emergent serious AEs, and hyperkalemia AEs

†Study duration and the number of study visits will depend on the time of enrollment of the patient. ‡Starting dose of finerenone: 10 mg once daily if eGFR is ≥25 mL/min/1.73 m^2 to <60 mL/min/1.73 m^2 or 20 mg once daily if eGFR is ≥60 mL/min/1.73 m^2 at screening visit. Finerenone will be up- or downtitrated based on potassium and eGFR levels. § All participants will stay in the study until the last randomized participant has reached 32 months of treatment.
ACEi, angiotensin-converting enzyme inhibitor; AE, adverse event; ARB, angiotensin receptor blocker; CV, cardiovascular; eGFR, estimated glomerular filtration rate; FIND-CKD, **FI**nerenone, in addition to standard of care, on the progression of kidney disease in patients with **N**on-**D**iabetic **C**hronic **K**idney **D**isease; HHF, hospitalization for heart failure; EOT, end of treatment; RND, randomization; SGLT2, sodium–glucose cotransporter 2; UACR, urinary albumin:creatinine ratio. Presented at the American Society of Nephrology Kidney Week, Philadelphia, Pennsylvania, November 2-5, 2023.

Enrollment: Global Screening and Randomization

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The first patient was enrolled in FIND-CKD in September 2021; enrollment† was completed in May 2023.

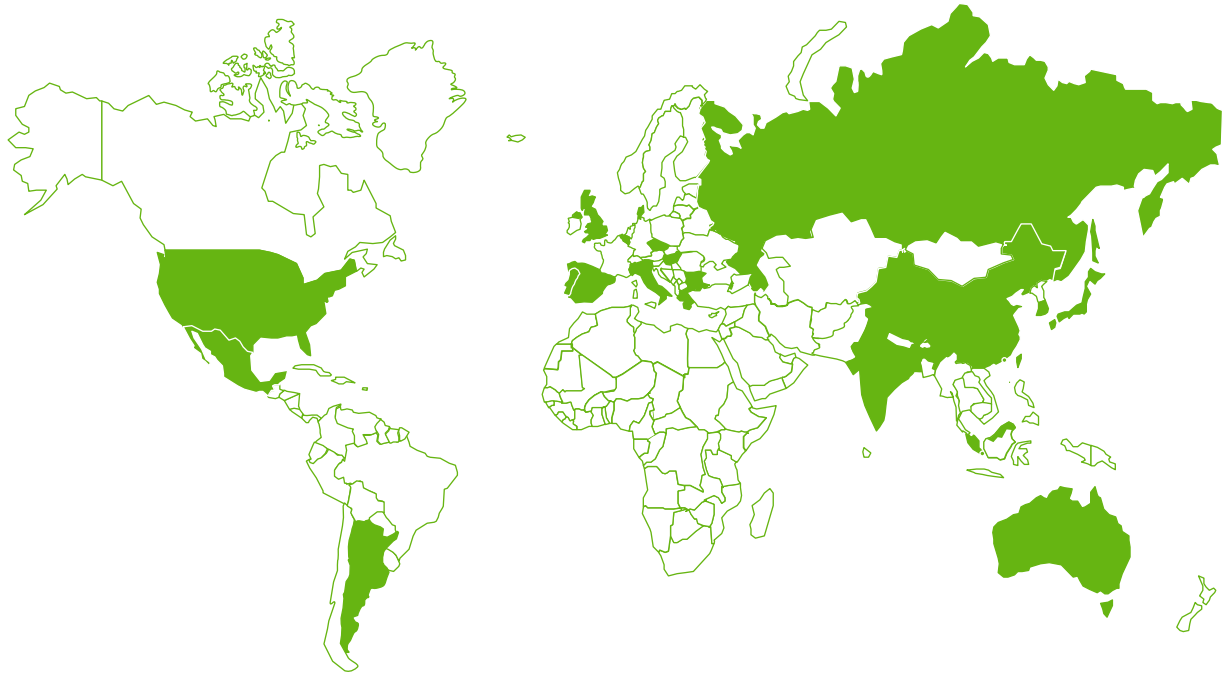
3231
screened

1584
randomized

Across **24** countries

84
randomized to participate in DCT model

DCT elements are made available to patients in **8** countries in North and Latin America, Asia, Europe, and Australia



†Participants enrolled in Australia, Argentina, Belgium, Bulgaria, China, Czech Republic, Denmark, Greece, Hong Kong, Hungary, India, Israel, Italy, Japan, Malaysia, Mexico, Portugal, Russian Federation, South Korea, Spain, Singapore, Taiwan, United Kingdom, and United States of America.
DCT, decentralized clinical trial; FIND-CKD, **FI**nerenone, in addition to standard of care, on the progression of kidney disease in patients with **N**on-**D**iabetic **C**hronic **K**idney **D**isease. Presented at the American Society of Nephrology Kidney Week, Philadelphia, Pennsylvania, November 2-5, 2023.

Baseline Demographics and Disease Characteristics†

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Characteristic	Total (N=1584)
Age, years, mean (SD)	54.7 (14.3)
Sex, male, n (%)	1049 (66.2)
Race, n (%)	
Asian	866 (54.7)
White	648 (40.9)
Black	37 (2.3)
Other	33 (2.1)
Ethnicity, n (%)	
Non-Hispanic	1461 (92.2)
Hispanic	111 (7.0)
Region, n (%)	
Asia	844 (53.3)
Europe and Oceania	535 (33.8)
North America	132 (8.3)
Latin America	73 (4.6)

Characteristic	Total (N=1584)
eGFR, mL/min/1.73 m^2, mean (SD)	46.7 (16.1)
eGFR category, mL/min/1.73 m^2, n (%)	
<25	23 (1.5)
25 to <45	821 (51.8)
45 to <60	423 (26.7)
≥60	317 (20.0)
UACR, mg/g, median (IQR)	818.9 (577.4-1244.0)
UACR category, mg/g, n (%)	
<300	63 (4.0)
300 to ≤1000	929 (58.6)
>1000	592 (37.4)
BMI, kg/m^2, mean (SD)	27.6 (5.6)
SBP, mmHg, mean (SD)	129.5 (14.1)
DBP, mmHg, mean (SD)	80.0 (9.6)
HbA1c, % (SD)	5.5 (0.4)
Serum potassium, mmol/L, mean (SD)	4.5 (0.4)

†Clinical variables of interest are shaded in red. BMI, body mass index; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; HbA1c, glycated hemoglobin; IQR, interquartile range; SBP, systolic blood pressure; SD, standard deviation; UACR, urinary albumin:creatinine ratio. Presented at the American Society of Nephrology Kidney Week, Philadelphia, Pennsylvania, November 2-5, 2023.

Baseline Kidney Disease Etiology, CVD History, and Concomitant Medications

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In FIND-CKD, historical kidney biopsies from patients were available for 787 (49.7%) patients.
Historical kidney biopsies were available for 42% and 36% of patients without diabetes in the EMPA-KIDNEY and DAPA-CKD trials, respectively.[1,2]

Kidney disease etiology, n (%)	Total (N=1584)
Hypertensive/ischemic nephropathy	460 (29.0)
Chronic glomerulonephritis	903 (57.0)
IgAN	417 (26.3)
FSGS	215 (13.6)
Primary FSGS	109 (6.9)
Secondary FSGS	106 (6.7)
Membranous nephropathy	91 (5.7)
Mesangial proliferative glomerulonephritis†	26 (1.6)
Other chronic glomerulonephritis	154 (9.7)
Other	57 (3.6)
Unknown	164 (10.4)

CVD history and concomitant medications, n (%)	Total (N=1584)
Hypertension	1396 (88.1)
Atherosclerotic CVD	189 (11.9)
Atrial fibrillation	59 (3.7)
Heart failure	35 (2.2)
RAASis‡	1581 (99.8)
ACEis‡	435 (27.5)
ARBs‡	1146 (72.3)
SGLT2 inhibitors	267 (16.9)
Potassium-lowering agents	58 (3.7)
Potassium supplements	20 (1.3)
Beta-blockers	403 (25.4)
Diuretics	282 (17.8)
Loop diuretics	128 (8.1)
Thiazide diuretics	116 (7.3)
Calcium channel blockers	794 (50.1)
Statins	851 (53.7)

†Defined as occurrence of one of the following non-pre-specified terms: glomerulonephritis membranoproliferative, glomerulonephritis proliferative, mesangioproliferative glomerulonephritis. ‡According to the protocol, all patients were required to use an ACEi or ARB if tolerated. ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CVD, cardiovascular disease; DAPA-CKD, **D**apagliflozin **A**nd **P**revention of **A**dverse outcomes in **C**hronic **K**idney **D**isease; EMPA-KIDNEY, A multicentre international randomized parallel group double-blind placebo-controlled clinical trial of **EMPA**gliflozin once daily to assess cardio-renal outcomes in patients with chronic **KIDNEY** disease; FIND-CKD, **FI**nerenone, in addition to standard of care, on the progression of kidney disease in patients with **N**on-**D**iabetic **C**hronic **K**idney **D**isease; FSGS, focal segmental glomerulosclerosis; IgAN, immunoglobulin A nephropathy; RAASi, renin–angiotensin–aldosterone system inhibitor; SGLT2, sodium–glucose cotransporter 2.

1. Wheeler DC, et al. *Nephrol Dial Transplant*. 2020;35:1700-1711. 2. The EMPA-KIDNEY Collaborative Group. *Nephrol Dial Transplant*. 2022;37:1317-1329. Presented at the American Society of Nephrology Kidney Week, Philadelphia, Pennsylvania, November 2-5, 2023.

Kidney Disease Characteristics by SGLT2 Inhibitor Use at Baseline

FIND-CKD

Patients using SGLT2 inhibitors at baseline had slightly higher UACR versus those who were not.
Mean eGFR was similar across patients who were receiving SGLT2 inhibitors versus those who were not.

	Receiving an SGLT2 inhibitor at baseline (n, percent of total trial population)	
	Yes (n=267; 16.9%)	No (n=1317; 83.1%)
eGFR, mL/min/1.73 m^2, mean (SD)	45.6 (15.8)	46.9 (16.1)
eGFR category, mL/min/1.73 m^2, n (%)		
<25	4 (1.5)	19 (1.4)
25 to <45	151 (56.6)	670 (50.9)
45 to <60	63 (23.6)	360 (27.3)
≥60	49 (18.4)	268 (20.3)
UACR, mg/g, median (IQR)	871.9 (619.2-1409.1)	808.3 (566.6-1218.5)
UACR category, mg/g, n (%)		
<300	6 (2.2)	57 (4.3)
300 to ≤1000	148 (55.4)	781 (59.3)
>1000	113 (42.3)	479 (36.4)

eGFR, estimated glomerular filtration rate; IQR, interquartile range; SD, standard deviation; SGLT2, sodium–glucose cotransporter 2; UACR, urinary albumin:creatinine ratio. Presented at the American Society of Nephrology Kidney Week, Philadelphia, Pennsylvania, November 2-5, 2023.

Conclusions

FIND-CKD

FIND-CKD will examine the potential for expanding the role of finerenone for the treatment of CKD beyond T2D.

1

The beneficial effects of finerenone on progression of kidney disease have already been demonstrated in patients with CKD and T2D.[1-3]

2

FIND-CKD includes patients with non-diabetic CKD etiologies, including hypertension and chronic glomerulonephritis such as IgAN and FSGS, who are at risk of progression.

3

The primary endpoint in FIND-CKD is the total eGFR slope, which is an accepted surrogate endpoint for clinical trials investigating kidney disease progression.[1,4-8]

4

The FIND-CKD trial will determine the efficacy of finerenone for slowing kidney disease progression in patients with CKD without diabetes, providing insight across multiple identifiable etiologies.

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; FIND-CKD, **FI**nerenone, in addition to standard of care, on the progression of kidney disease in patients with **N**on-**D**iabetic **C**hronic **K**idney **D**isease; FSGS, focal segmental glomerulosclerosis; IgAN, immunoglobulin A nephropathy; IQR, interquartile range; SD, standard deviation; SGLT2, sodium–glucose cotransporter 2; T2D, type 2 diabetes; UACR, urinary albumin:creatinine ratio.

1. Bakris GL, et al. *N Engl J Med*. 2020;383:2219-2229. 2. Pitt B, et al. *N Engl J Med*. 2021;385:2252-2263. 3. Agarwal R, et al. *Eur Heart J*. 2022;43:474-484. 4. Greene T, et al. *J Am Soc Nephrol*. 2019;30:1756-1769. 5. Torres VE, et al. *N Engl J Med*. 2017;377:1930-1942. 6. Komers R, et al. *Kidney Int Rep*. 2020;5:494-502. 7. Inker LA, et al. *Nat Med*. 2023;29:1867-1876. 8. EMA. Draft qualification opinion for GFR slope as a surrogate endpoint in RCT for CKD. 2023. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/draft-qualification-opinion-gfr-slope-surrogate-endpoint-rct-ckd_en.pdf. Accessed October 10, 2023. Presented at the American Society of Nephrology Kidney Week, Philadelphia, Pennsylvania, November 2-5, 2023.