



Efficacy and safety of finerenone by age in patients with chronic kidney disease and type 1 diabetes

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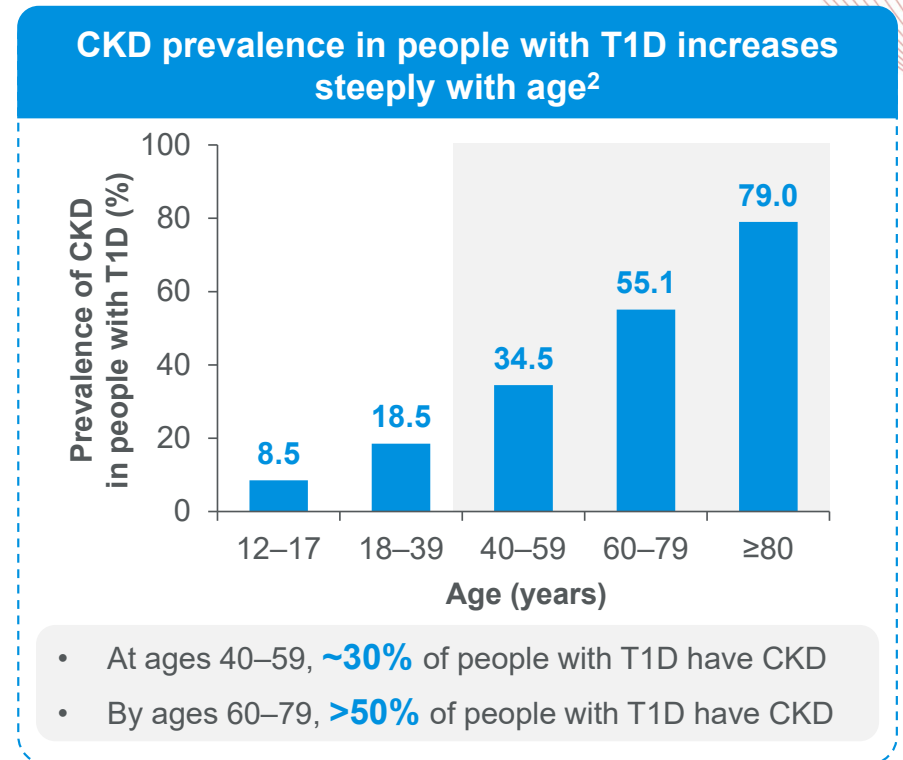
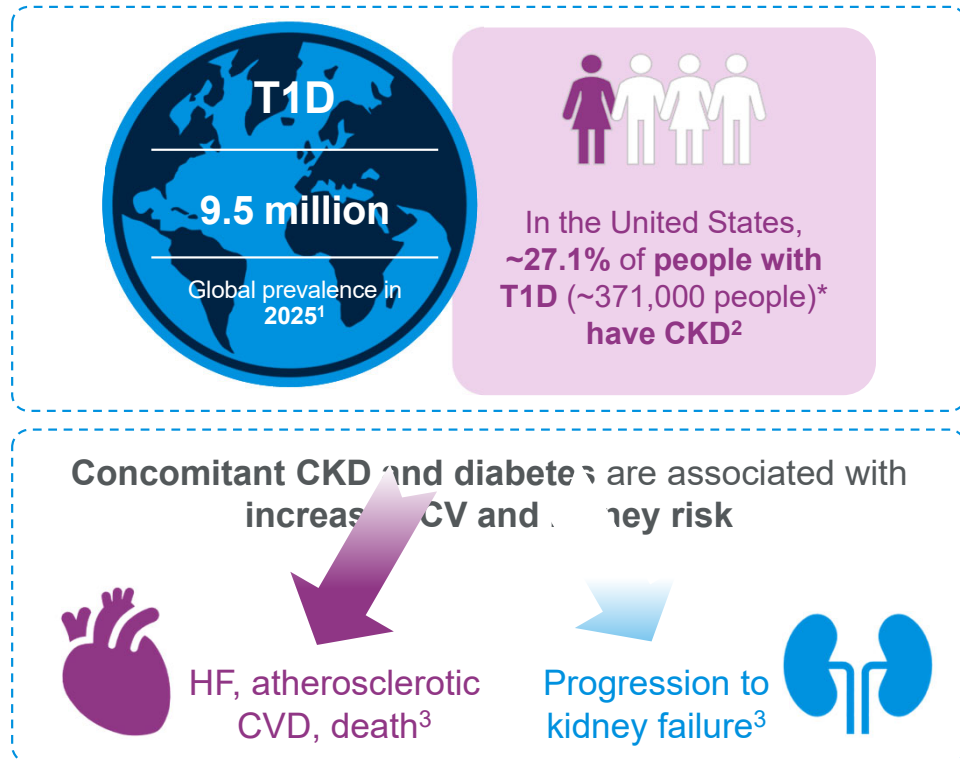
On behalf of Hiddo J.L. Heerspink, David Z.I. Cherney,
Per-Henrik Groop, Janet B. McGill, Peter Rossing, Li Mao,
Niels Jongs, Robert Lawatscheck, Julie Russell,
Richard E. Pratley and the FINE-ONE investigators

Speaker disclosures

- Consultancy for Bayer, Novo Nordisk, and Travers Therapeutics
- Recent or current research support to institution from Bayer, Boehringer Ingelheim, and ProKidney

The FINE-ONE trial was funded by Bayer

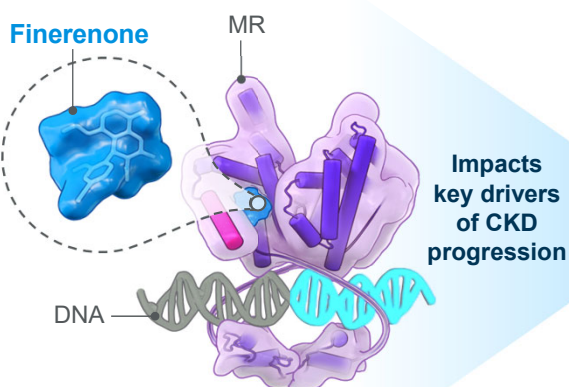
The prevalence of CKD in people with T1D increases with age



Despite RASi treatment, kidney, CV and mortality risk remain substantial for people with T1D, with no advancement in therapy options since the 1990s^{4,5}

Finerenone blocks MR overactivation and reduces UACR, which can be used as a bridging biomarker for benefits in long-term kidney outcomes

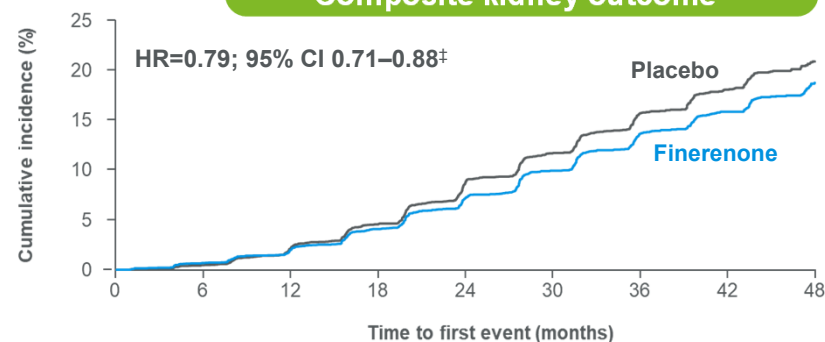
MR overactivation blockade¹⁻³



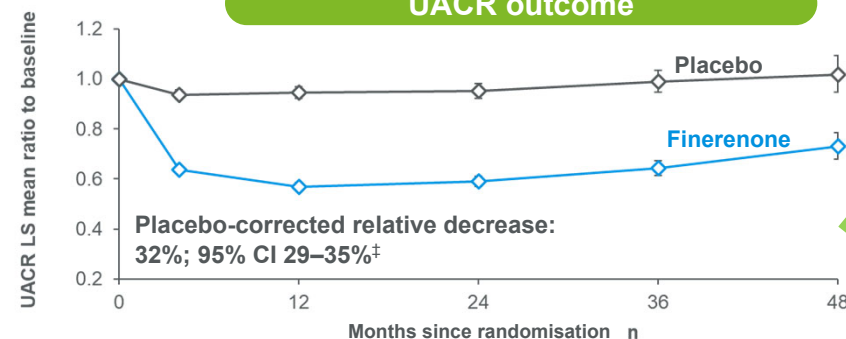
Slows CKD and HF progression¹⁻³

Key outcomes in people with CKD and T2D (FIDELITY*)²

Composite kidney outcome[#]



UACR outcome



87%
of effect
explained
by early
UACR
reduction⁴

*Pooled analysis combining patient-level data from the phase III finerenone trials FIDELIO-DKD and FIGARO-DKD; [#]time to kidney failure, sustained $\geq 40\%$ decrease in eGFR from baseline, or renal death; [†]based on a dataset restricted to participants with UACR ≥ 200 mg/g (22.6 mg/mmol) and eGFR ≥ 25 and < 90 ml/min/1.73 m²; CI, confidence interval; eGFR, estimated glomerular filtration rate; HR, hazard ratio; LS, least-squares; MR, mineralocorticoid receptor; T2D, type 2 diabetes; UACR, urine albumin-to-creatinine ratio
1. Kintscher U, et al. *Br J Pharmacol* 2022;179:3220-3234; 2. Agarwal R, et al. *Eur Heart J* 2022;43:474-484; 3. Agarwal R, et al. *Nephrol Dial Transplant* 2022;37:1014-1023; 4. Heerspink HJL, et al. *Diabetes Res Clin Pract* 2023;204:110908

The FINE-ONE trial demonstrated that finerenone significantly reduced UACR in people with T1D and CKD compared with placebo¹

FINE-ONE was a global, randomised, phase III clinical trial¹



Primary outcome: efficacy

- Change in UACR from baseline (ratio to baseline) over 6 months

Secondary outcomes: safety

- Number of participants with TEAEs or serious TEAEs
- Number of participants with hyperkalaemia (an AESI)

In this FINE-ONE post hoc analysis, we examine the efficacy and safety of finerenone by age



Key inclusion criteria

- Aged ≥18 years
- T1D (continuously treated with insulin)
- HbA1c at screening <10%
- CKD and eGFR ≥25–<90 ml/min/1.73 m² and UACR ≥200–<5000 mg/g
- Serum [K⁺] ≤4.8 mmol/l
- Stable dose of ACEi/ARB for >1 month prior to screening visit



Key exclusion criteria

- T2D, other kidney disease or kidney transplantation
- Mean BP >160/100 mmHg or SBP <90 mmHg
- Symptomatic HFrEF with class 1A indication for MRAs
- Current or previous[#] treatment with an SGLT-2i or GLP-1RA

Finerenone received US FDA approval in September 2026 to reduce UACR, which is expected to reduce the risk of sustained eGFR decline and ESKD in adults with CKD associated with T1D mellitus²
In the EU, finerenone is only indicated for the treatment of CKD (with albuminuria) associated with T2D in adults and for the treatment of symptomatic chronic HF with LVEF ≥40% in adults³

*Initiated at 20 mg od if screening eGFR ≥60 ml/min/1.73 m² and at 10 mg od if screening eGFR ≥25–<60 ml/min/1.73 m²; dose increase to 20 mg od was allowed from Month 1 if serum [K⁺] ≤4.8 mmol/l and eGFR did not decrease by ≥30% since the last visit; [#]within 8 weeks prior to the screening visit

ACEi, angiotensin-converting enzyme inhibitor; AESI, adverse event of special interest; ARB, angiotensin receptor blocker; BP, blood pressure; ESKD, end-stage kidney disease;

GLP-1RA, glucagon-like peptide-1 receptor agonist; HbA1c, glycated haemoglobin; HFrEF, heart failure with reduced ejection fraction; [K⁺], potassium concentration; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonist; od, once daily; R, randomisation; SBP, systolic blood pressure; SGLT-2i, sodium-glucose co-transporter-2 inhibitor; TEAE, treatment-emergent adverse event

1. Heerspink HJL, et al. *N Engl J Med* 2026;394:947–957; 2. Bayer AG. KERENDIA® (finerenone) Prescribing Information. 2026. [accessed 24 Sep 2026];

3. SmPC: Bayer AG. KERENDIA® (finerenone) Summary of Product Characteristics. 2026. [accessed 24 Sep 2026]

Most baseline characteristics were balanced between participants above and below the median age of 52 years



FINE-ONE median age: 52 years

Characteristic	Finerenone		Placebo	
	≤52 years (n=64)	>52 years (n=56)	≤52 years (n=64)	>52 years (n=58)
Age , years, mean	40	64	41	64
Sex , male, n (%)	41 (64)	38 (68)	40 (63)	39 (67)
Race , n (%)				
White	39 (61)	46 (82)	41 (64)	49 (85)
Asian	17 (27)	6 (11)	19 (30)	6 (10)
Black	6 (9)	3 (5)	3 (5)	3 (5)
Other*	2 (3)	1 (2)	1 (2)	0
BMI , [#] kg/m ² , mean	28	27	27	27
eGFR , ml/min/1.73 m ² , mean	60	58	62	55
UACR , mg/g, median (Q1–Q3)	655 (374–1286)	518 (253–966)	522 (301–1305)	470 (272–910)

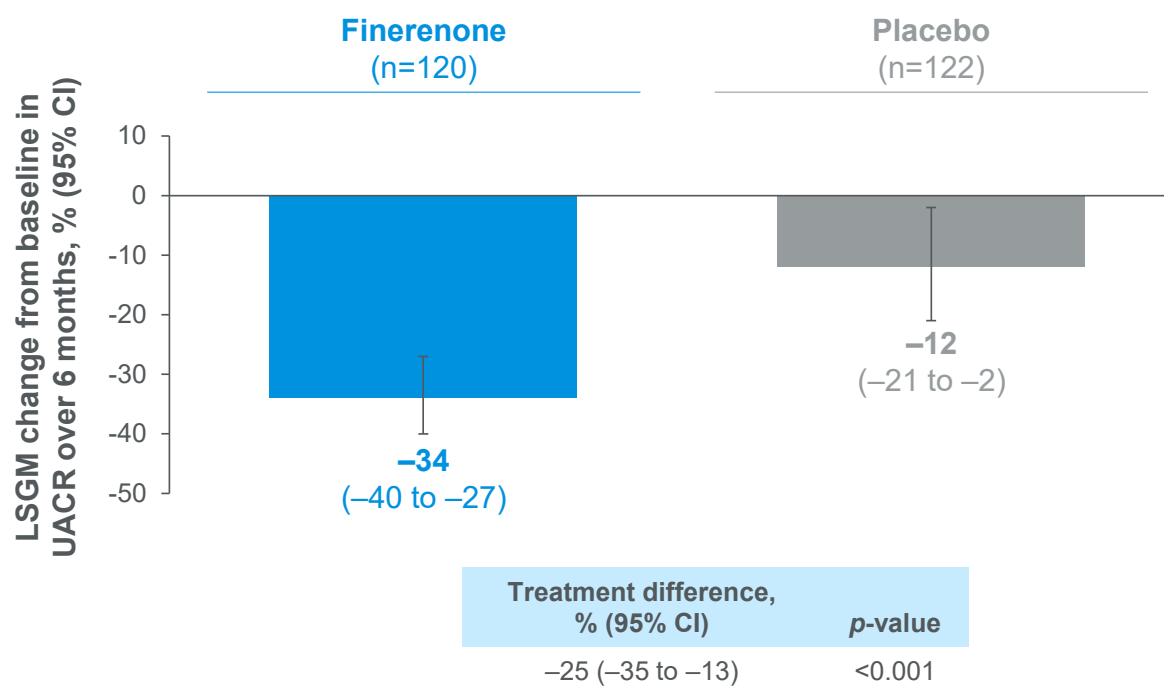
Characteristic	Finerenone		Placebo	
	≤52 years (n=64)	>52 years (n=56)	≤52 years (n=64)	>52 years (n=58)
Serum [K⁺] , mmol/l, mean	4.7	4.6	4.6	4.5
BP , mmHg, mean				
Systolic	134	139	130	138
Diastolic	82	74	80	73
HbA1c , [‡] %, mean	7.9	7.6	7.5	7.5
Duration of T1D , years, mean	26	39	25	39
ACEi use , n (%)	31 (48)	29 (52)	22 (34)	30 (52)
ARB use , n (%)	33 (52)	27 (48)	41 (64)	27 (47)



Most characteristics were balanced between groups, although median UACR was more variable

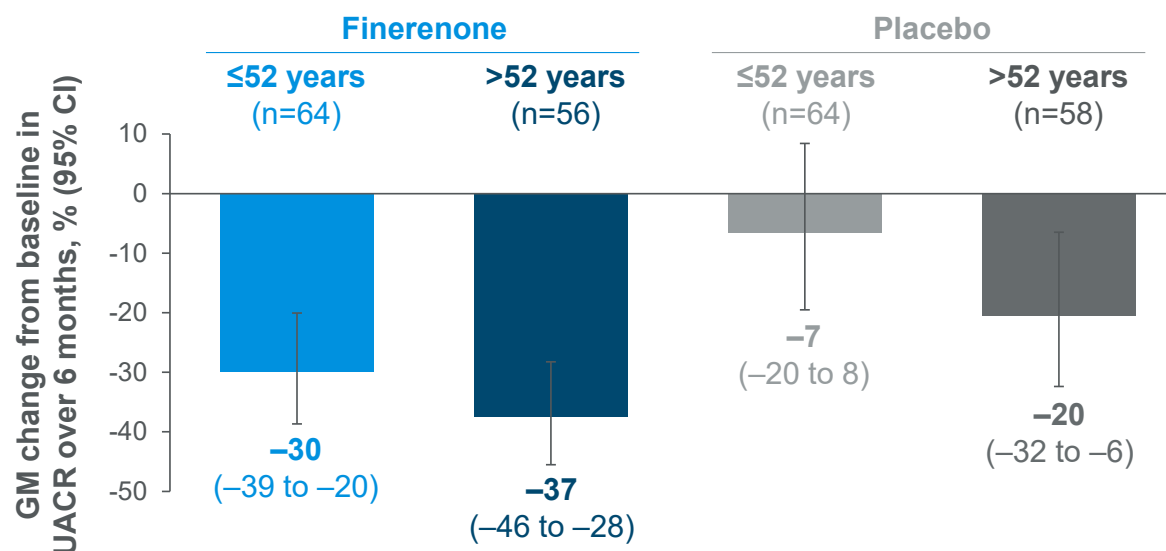
Finerenone significantly reduced UACR over 6 months in the overall population

Mean change in UACR over 6 months*



The reduction in UACR over 6 months with finerenone was not modified by age

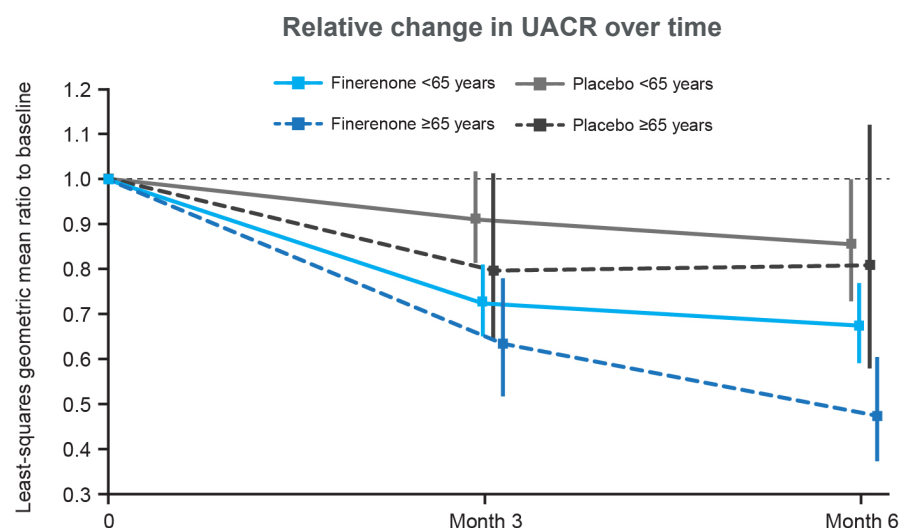
Mean change in UACR over 6 months, by age group (below and above the median age)



Baseline age	Treatment difference, % (95% CI)	p-value	<i>p</i> _{interaction}
≤52 years	-25 (-39 to -9)	0.005	0.585
>52 years	-21 (-36 to -3)	0.026	

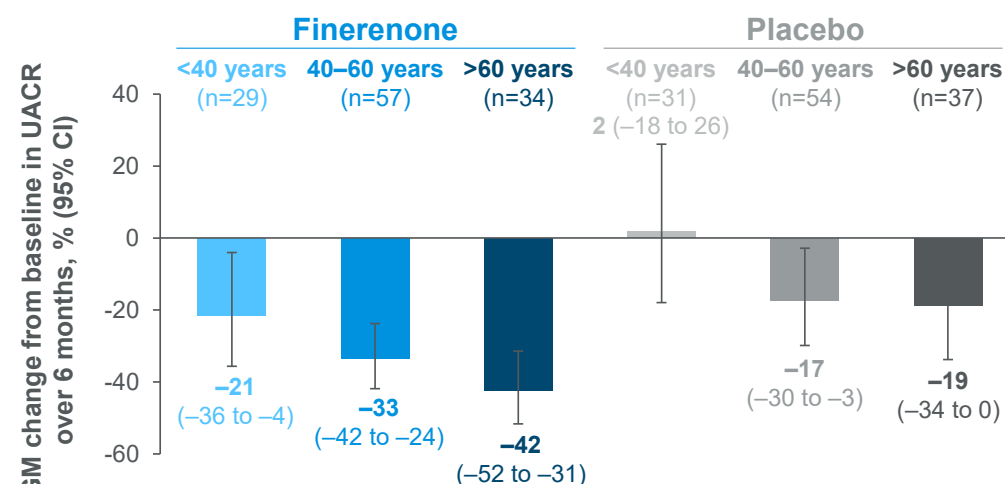
The treatment effect of finerenone on UACR was consistent across multiple other age data-cuts

<65/≥65 years data-cut*



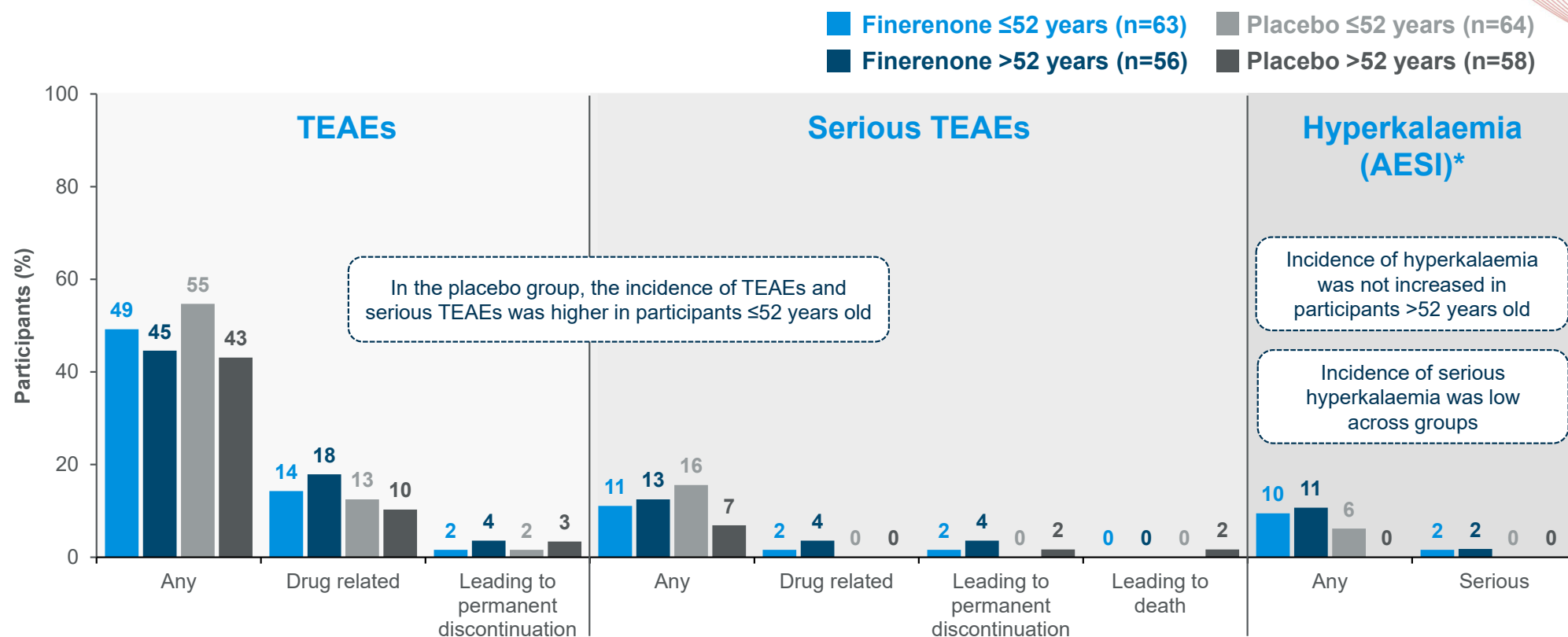
Baseline age	Treatment effect [#]	p-value	<i>p</i> _{interaction}
≤65 years	0.79 (0.65–0.96)	0.021	0.193
>65 years	0.59 (0.39–0.88)	0.009	

<40/40–60/>60 years data-cut[‡]



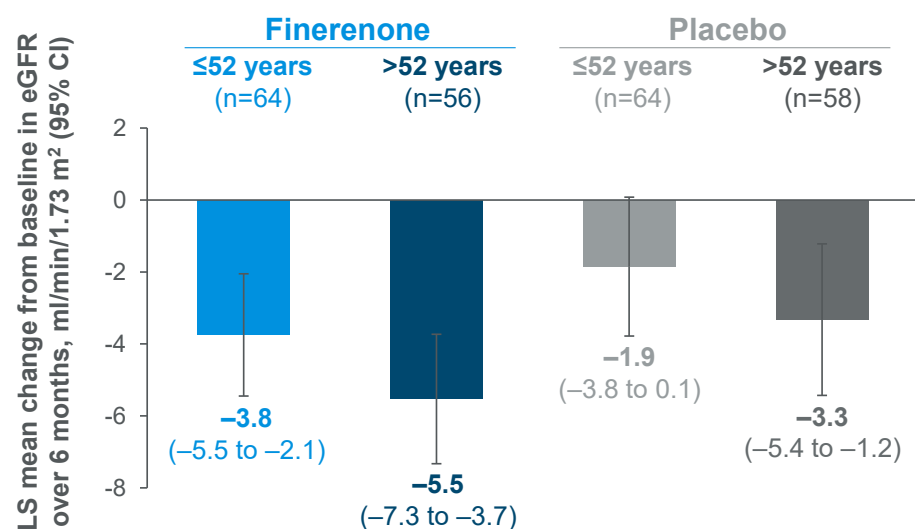
Baseline age	Treatment difference, % (95% CI)	p-value	<i>p</i> _{interaction}
<40 years	-23 (-42 to 3)	0.083	0.244
40–60 years	-19 (-35 to 0)	0.046	
>60 years	-29 (-46 to -7)	0.012	

The overall incidence of TEAEs was similar between the finerenone and placebo groups across age groups



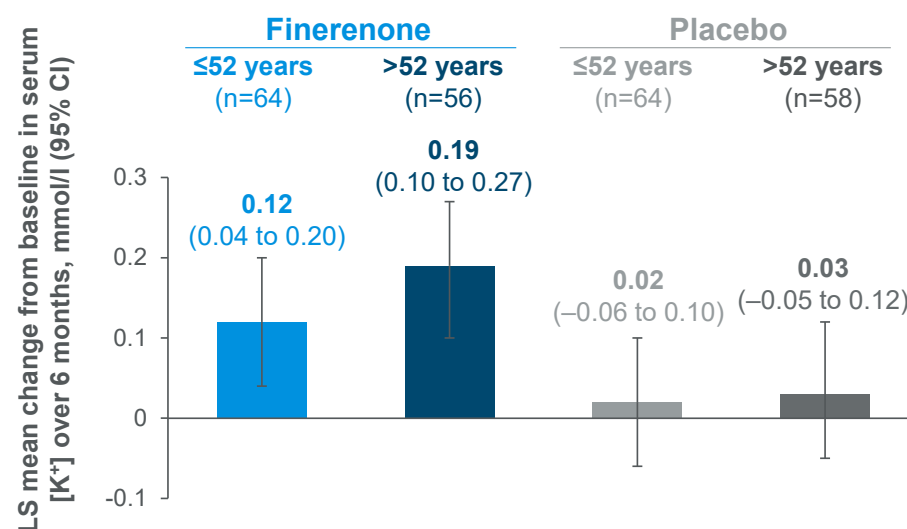
The effects of finerenone on eGFR and serum potassium were not modified by age

Mean change in eGFR over 6 months



Baseline age	Treatment difference, ml/min/1.73 m ² (95% CI)	p-value	<i>p</i> _{interaction}
≤52 years	-1.9 (-4.5 to 0.7)	0.144	0.759
>52 years	-2.2 (-5.0 to 0.6)	0.116	

Mean change in serum [K⁺] over 6 months



Baseline age	Treatment difference, mmol/l (95% CI)	p-value	<i>p</i> _{interaction}
≤52 years	0.10 (-0.02 to 0.21)	0.090	0.231
>52 years	0.15 (0.03 to 0.28)	0.014	

Summary and conclusion



In this **FINE-ONE** post hoc analysis, we examined **whether age modified the efficacy and safety of finerenone** in patients with T1D and CKD

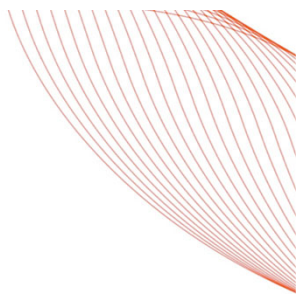


Finerenone significantly reduced UACR over 6 months compared with placebo **across multiple age groups**



The overall incidence of **AEs was similar across age groups** and treatment arms, and the effects of finerenone on **eGFR and serum potassium were not modified by age**

Finerenone **reduced albuminuria** and had a **favourable benefit–risk profile irrespective of age**, and may therefore **reduce adverse kidney outcomes** across a spectrum of adults with CKD and T1D



Backup options

Baseline characteristics by age (below and above 65 years)



FINE-ONE median age: 52 years

Characteristic	Finerenone		Placebo	
	<65 years (n=94)	≥65 years (n=26)	<65 years (n=98)	≥65 years (n=24)
Age , years, mean	46	70	47	71
Sex , male, n (%)	63 (67)	16 (62)	67 (68)	12 (50)
Race , n (%)				
White	64 (68)	21 (81)	70 (71)	20 (83)
Asian	19 (20)	4 (15)	23 (24)	2 (8)
Black	9 (10)	0	4 (4)	2 (8)
Other*	2 (2)	1 (4)	1 (1)	0
BMI , [#] kg/m ² , mean	28	27	28	26
eGFR , ml/min/1.73 m ² , mean	59	58	60	56
UACR , mg/g, median (Q1–Q3)	625 (331–1301)	518 (319–788)	522 (302–1287)	327 (232–678)

Characteristic	Finerenone		Placebo	
	<65 years (n=94)	≥65 years (n=26)	<65 years (n=98)	≥65 years (n=24)
Serum [K⁺] , mmol/l, mean	4.6	4.5	4.6	4.4
BP , mmHg, mean				
Systolic	135	142	133	140
Diastolic	80	72	78	71
HbA1c , [‡] %, mean	7.8	7.7	7.5	7.3



Most characteristics were balanced between groups, although median UACR was more variable



Systolic BP was lower, but diastolic BP was higher in participants <65 years vs ≥65 years

Baseline characteristics by age (<40 / 40–60 / >60 years)

Characteristic	Finerenone			Placebo		
	<40 years (n=29)	40–60 years (n=57)	>60 years (n=34)	<40 years (n=31)	40–60 years (n=54)	>60 years (n=37)
Age, years, mean	32	51	68	35	51	68
Sex, male, n (%)	14 (48)	43 (75)	22 (65)	23 (74)	34 (63)	22 (60)
Race, n (%)						
White	15 (52)	43 (75)	27 (79)	22 (71)	37 (69)	31 (84)
Asian	10 (35)	8 (14)	5 (15)	7 (23)	15 (28)	3 (8)
Black	2 (7)	6 (11)	1 (3)	2 (7)	1 (2)	3 (8)
Other*	2 (7)	0	1 (3)	0	1 (2)	0
BMI, [#] kg/m ² , mean	28	28	27	28	27	27
eGFR, ml/min/1.73 m ² , mean	58	60	58	66	57	55
UACR, mg/g, median (Q1–Q3)	939 (486–1919)	549 (300–958)	508 (257–802)	561 (311–1079)	520 (253–1483)	423 (278–910)
Serum [K ⁺], mmol/l, mean	4.7	4.6	4.5	4.7	4.6	4.5
SBP/DBP, mmHg, mean	129/84	138/79	141/73	131/84	132/75	140/73
HbA1c, [‡] %, mean	8.1	7.7	7.7	7.3	7.5	7.6



Most characteristics were balanced between groups, although median UACR was variable

SBP increased with age, DBP decreased with age



Finerenone recipients <40 years old had markedly higher UACR and HbA1c than other groups

Safety by age (below and above 65 years)

