



Effect of BMI on kidney–cardio outcomes with finerenone in a broad CKD population (INFINITY)

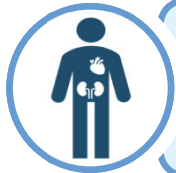
Peter Rossing on behalf of:

Carolyn SP Lam, Rajiv Agarwal, David ZI Cherney, Brendon L Neuen, Vlado Perkovic, Katherine R Tuttle, Christoph Wanner, Pantelis Sarafidis, Luis M Ruilope, J David Smeijer, Meike Brinker, Yoriko De Sanctis, and Hiddo JL Heerspink

Speaker disclosures:

Peter Rossing reports personal fees from Bayer during the conduct of the study; he has received research support and personal fees from AstraZeneca and Novo Nordisk, and personal fees from Abbott, Astellas, Boehringer Ingelheim, Eli Lilly and Company, Gilead, Mundipharma, Sanofi, and Vifor; all fees are given to Steno Diabetes Center Copenhagen

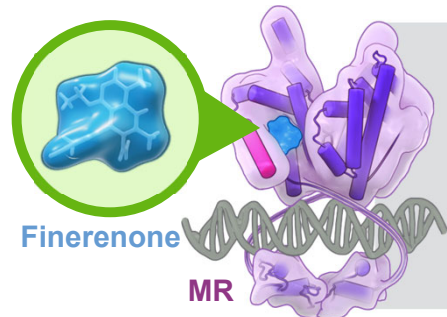
Background



- **Obesity** is a common risk factor for CKD development^{1–3} and increases risk of kidney disease progression and end stage kidney disease^{3,4}
- Obesity also **increases risk of cardiovascular diseases**^{3,4}



- **Aldosterone levels** are increased in individuals with obesity⁵
- **Excess aldosterone and MR activation** may be mediators of obesity-related increased kidney and cardiovascular risk⁶



Finerenone, a non-steroidal MRA, **reduced the risk of kidney disease progression and cardiovascular events** in the **INFINITY pooled analysis** of participants with CKD with a broad range of aetiologies and kidney function⁷



CKD, chronic kidney disease; MR, mineralocorticoid receptor; MRA, mineralocorticoid receptor antagonist

1. Brauer M, et al. *Lancet*. 2024;403:2162–2203; 2. Phelps N, et al. *Lancet*. 2024;403:1027–1050; 3. Furth SL, et al. *Kidney Int*. 2026;109:442–464; 4. Chang AR, et al. *BMJ*. 2019;364:k5301; 5. Puzantian H, et al. *J Clin Hypertension*. 2024;26:1384–1390; 6. Savarese G, et al. *Diabetologia*. 2024;67:246–262; 7. Neuen BL, et al. *Lancet*. 2026;407:2375–2386

Aims and methods



The **aims** of this prespecified analysis were to investigate:

- The impact of obesity (as measured by baseline BMI) on kidney–cardiovascular risk
- The effect of baseline BMI on the efficacy and safety of finerenone

FIDELIO-DKD

FIGARO-DKD

FIDELITY
N=12,990

FIND-CKD
N=1584

INFINITY
N=14,574

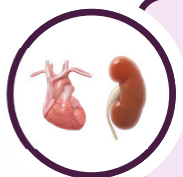
Participants* were stratified into 5 categories based on their baseline BMI (kg/m²):

R#
1:1

Finerenone 10 or 20 mg[‡] once daily

Placebo

	Non-Asian	Asian
Non-elevated (n=1406)	18.5–<25.0	18.5–<23.0
Overweight (n=4863)	25.0–<30.0	23.0–<27.5
Class I obesity (n=4809)	30.0–<35.0	27.5–<32.5
Class II obesity (n=2229)	35.0–<40.0	32.5–<37.5
Class III obesity (n=1173)	≥40.0	≥37.5



Outcomes:

- **Kidney composite:** Time to kidney failure[§] or sustained ≥57% decrease in eGFR

- **Kidney–CV composite:** Time to kidney failure[§], sustained ≥57% decrease in eGFR, HHF or CV death
- **Others:** CV composite (HHF or CV death), all-cause death
- **Safety:** TEAEs, SAEs and hyperkalaemia events

*With a recorded BMI ≥18.5 kg/m² at baseline; [‡]Participants were required to be receiving a maximum or stable dose of renin–angiotensin system inhibitor for ≥4 weeks before screening; [‡]10 mg for participants with an eGFR ≥25 to <60 ml/min/1.73 m² and 20 mg for those with an eGFR ≥60 ml/min/m²; after a month participants could up-titrate to the target dose (20 mg) if their serum potassium level was ≤4.8 mmol/l and their eGFR was stable.

[§]Kidney failure was defined as sustained eGFR <15 ml/min/1.73 m² or initiation of chronic dialysis or kidney transplantation

BMI, body mass index; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HHF, hospitalisation for heart failure; MI, myocardial infarction; SAEs, serious adverse events; TEAEs, treatment-emergent adverse events

Baseline demographics and characteristics

Characteristic	Non-elevated (n=1406)	Overweight (n=4863)	Class I obesity (n=4809)	Class II obesity (n=2229)	Class III obesity (n=1173)
Age, years, mean ± SD	63.8 (12.7)	64.7 (10.7)	64.1 (10.1)	62.2 (9.9)	60.6 (9.8)
Sex, male, n (%)	913 (64.9)	3589 (73.8)	3460 (71.9)	1460 (65.5)	638 (54.4)
Race, n (%)					
Asian	551 (39.2)	1639 (33.7)	1108 (23.0)	303 (13.6)	80 (6.8)
White	683 (48.6)	2802 (57.6)	3346 (69.6)	1724 (77.3)	925 (78.9)
Black	45 (3.2)	132 (2.7)	146 (3.0)	113 (5.1)	116 (9.9)
Other*	127 (9.0)	290 (6.0)	209 (4.3)	89 (4.0)	52 (4.4)
Region, n (%)					
Asia	534 (38.0)	1559 (32.1)	1018 (21.2)	264 (11.8)	64 (5.5)
Europe‡	503 (35.8)	2151 (44.2)	2561 (53.3)	1240 (55.6)	600 (51.2)
North America	146 (10.4)	534 (11.0)	674 (14.0)	452 (20.3)	363 (30.9)
Latin America	206 (14.7)	543 (11.2)	457 (9.5)	193 (8.7)	95 (8.1)
Other	17 (1.2)	76 (1.6)	99 (2.1)	80 (3.6)	51 (4.3)
BMI, kg/m², mean ± SD	22.5 (1.6)	26.9 (1.8)	31.6 (1.8)	36.7 (1.7)	44.1 (4.4)
Serum [K⁺], mmol/l, mean ± SD	4.4 (0.5)	4.4 (0.5)	4.4 (0.4)	4.3 (0.4)	4.3 (0.4)
eGFR, ml/min/1.73 m², mean ± SD	53.9 (20.9)	55.4 (20.4)	56.7 (21.4)	57.7 (22.2)	59.6 (24.0)
UACR, mg/g, median (Q1–Q3)	639.7 (292.4–1187.9)	569.2 (228.4–1162.5)	544.1 (225.2–1140.3)	546.3 (217.9–1168.1)	586.4 (237.5–1200.9)

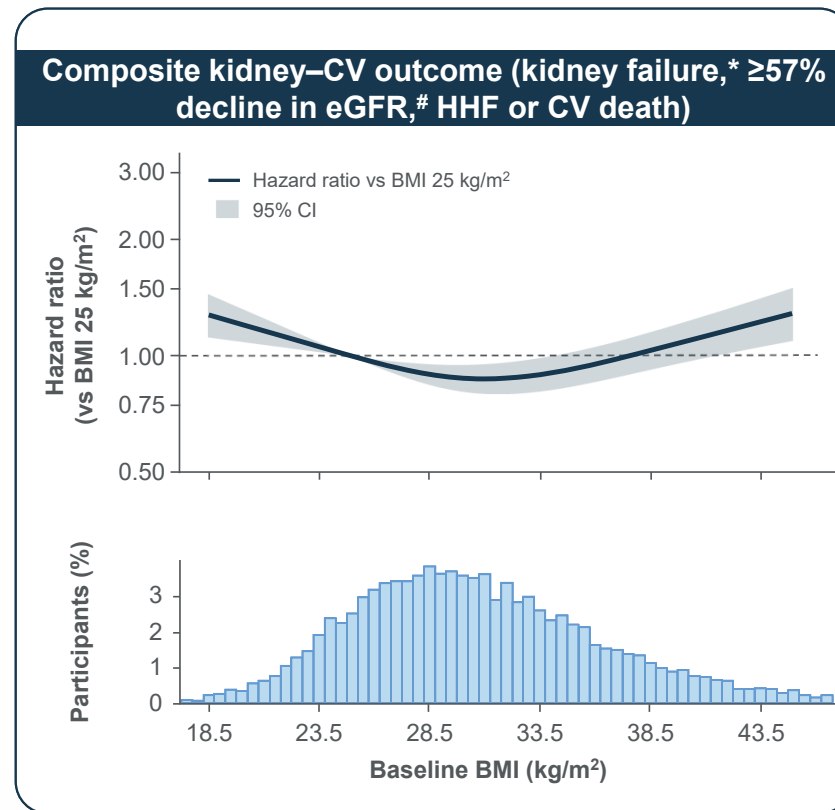
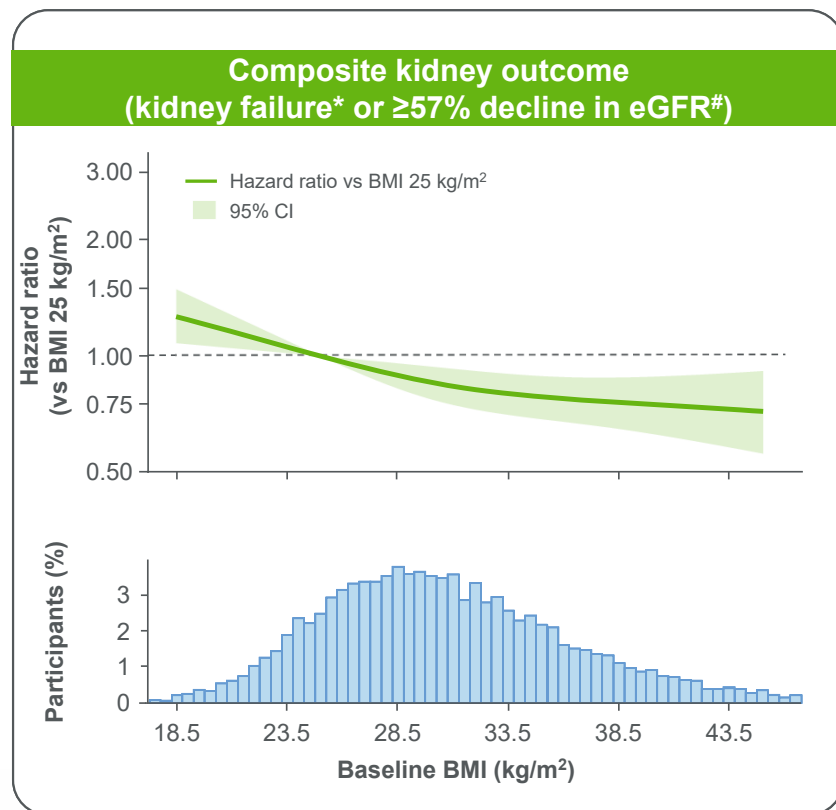
*Including American Indian or Alaska native, native Hawaiian or other Pacific islander, not reported or multiple; ‡Including the countries of Australia and Israel
 BMI, body mass index; eGFR, estimated glomerular filtration rate; [K⁺], potassium concentration; SD, standard deviation; UACR, urine albumin-to-creatinine ratio

Baseline demographics and characteristics

Characteristic	Non-elevated (n=1406)	Overweight (n=4863)	Class I obesity (n=4809)	Class II obesity (n=2229)	Class III obesity (n=1173)
SBP , mmHg, mean $\pm$ SD	132.9 (15.5)	135.5 (14.4)	136.5 (14.1)	137.2 (13.7)	137.2 (14.0)
HbA1c , %	7.0 (1.5)	7.3 (1.4)	7.6 (1.4)	7.8 (1.4)	7.9 (1.5)
Medical history , n (%)					
ASCVD	500 (35.6)	2069 (42.5)	2107 (43.8)	966 (43.3)	444 (37.9)
Atrial fibrillation	66 (4.7)	331 (6.8)	405 (8.4)	219 (9.8)	138 (11.8)
Heart failure	56 (4.0)	301 (6.2)	349 (7.3)	201 (9.0)	131 (11.2)
Medication use , n (%)					
ACEi	489 (34.8)	1739 (35.8)	1805 (37.5)	968 (43.4)	475 (40.5)
ARB	914 (65.0)	3118 (64.1)	2998 (62.3)	1263 (56.7)	698 (59.5)
Diuretics	404 (28.7)	1934 (39.8)	2522 (52.4)	1320 (59.2)	780 (66.5)
SGLT2i	95 (6.8)	345 (7.1)	396 (8.2)	196 (8.8)	103 (8.8)
Statins	879 (62.5)	3364 (69.2)	3489 (72.6)	1613 (72.4)	850 (72.5)

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ASCVD, atherosclerotic cardiovascular disease; HbA1c, glycated haemoglobin; SBP, systolic blood pressure; SD, standard deviation; SGLT2i, sodium-glucose co-transporter-2 inhibitor

Relationship between continuous baseline BMI and kidney, CV and mortality outcomes



Spline analyses were adjusted for treatment and include covariates age, sex, pooled race, region, baseline eGFR and log-transformed baseline UACR

*Defined as sustained eGFR ≤ 15 ml/min/1.73 m², initiation of dialysis or kidney transplantation. #From baseline for ≥ 4 weeks

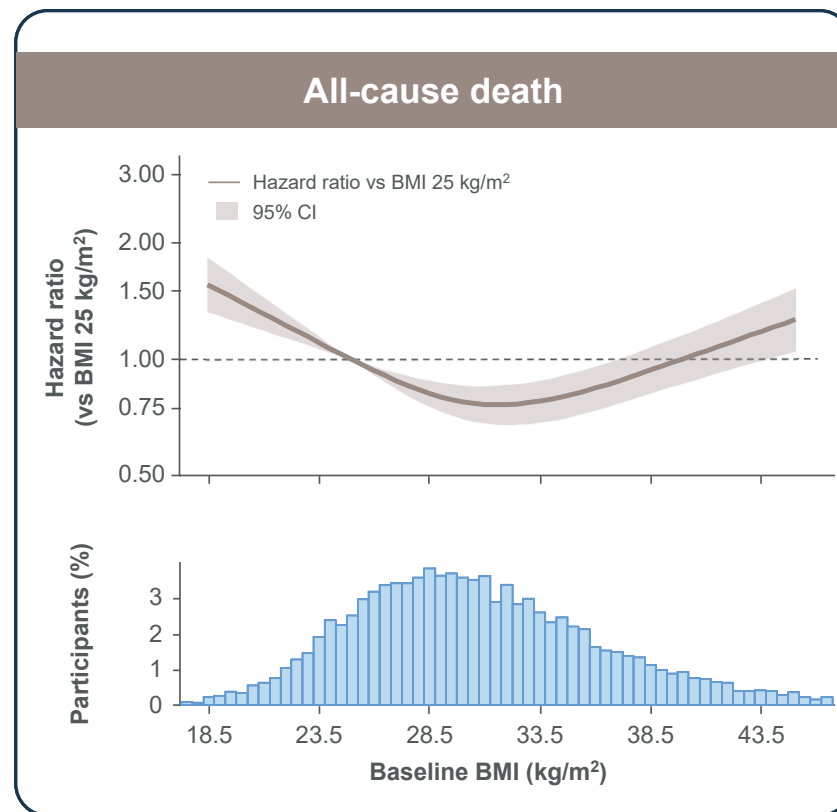
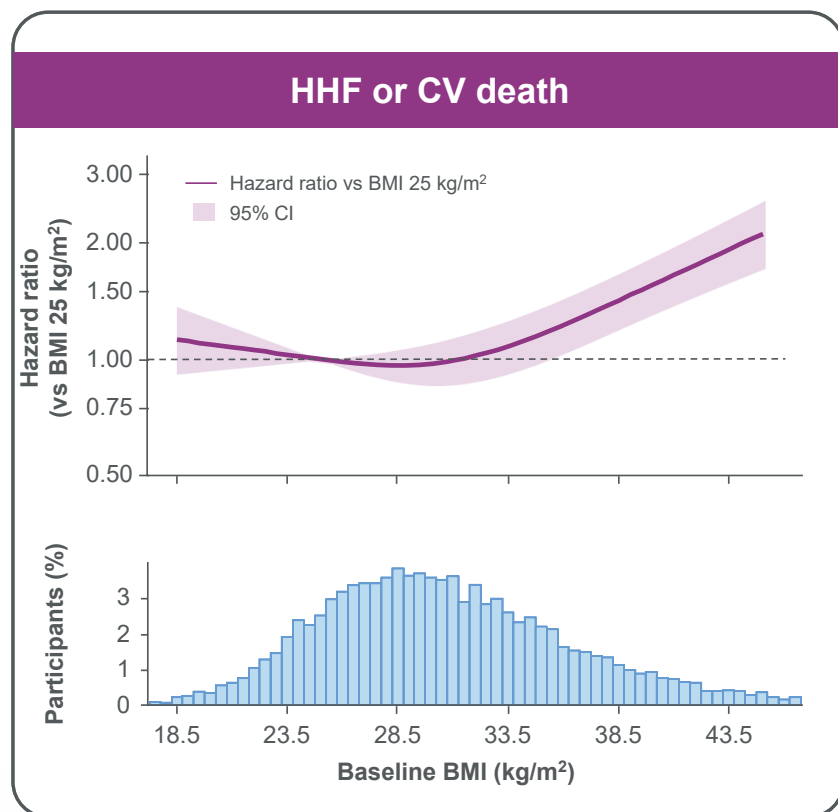
BMI, body mass index; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HHF, hospitalisation for heart failure; UACR, urine albumin-to-creatinine ratio

Slide 6

MW1 Dear GPC reviewers, Hiddo has confirmed he agrees with using adjusted models throughout. The adjustments have been noted in the footnotes on slides 6-11

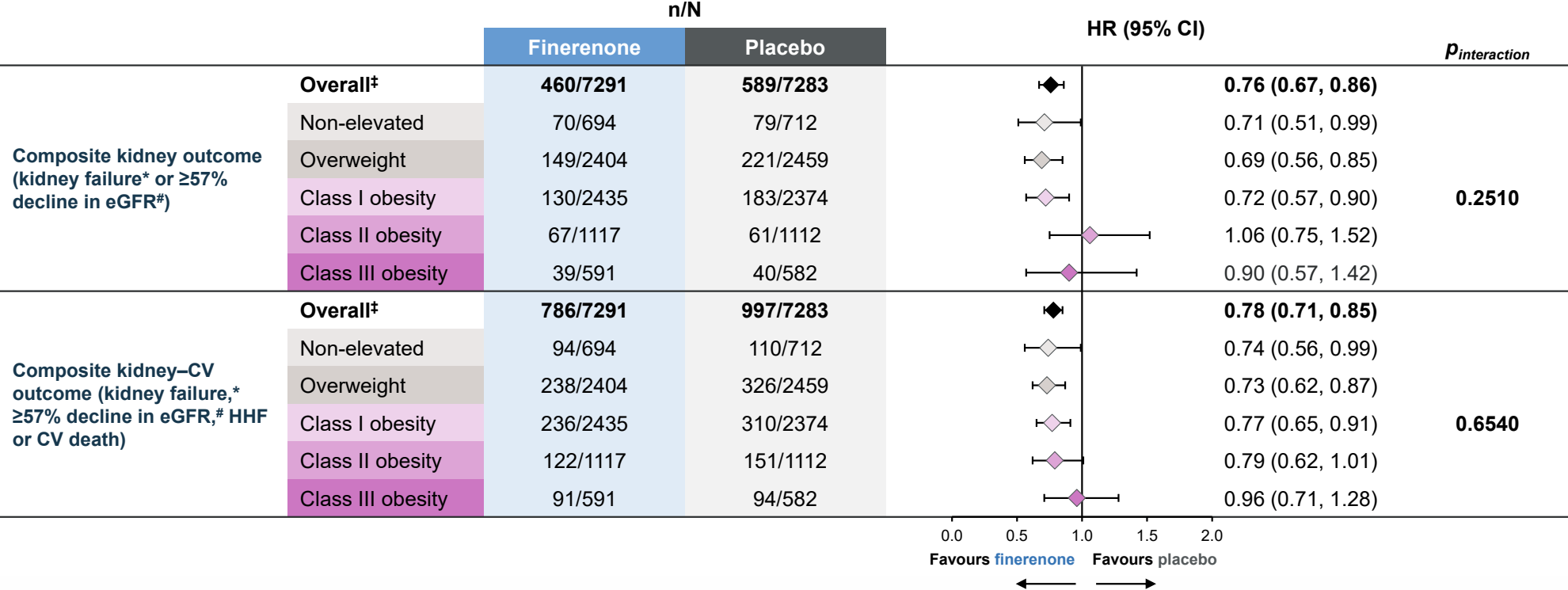
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Relationship between continuous baseline BMI and kidney, CV and mortality outcomes



Spline analyses were adjusted for treatment and include covariates age, sex, pooled race, region, baseline eGFR and log-transformed baseline UACR
BMI, body mass index; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HHF, hospitalisation for heart failure; UACR, urine albumin-to-creatinine ratio

Impact of baseline BMI category on finerenone efficacy



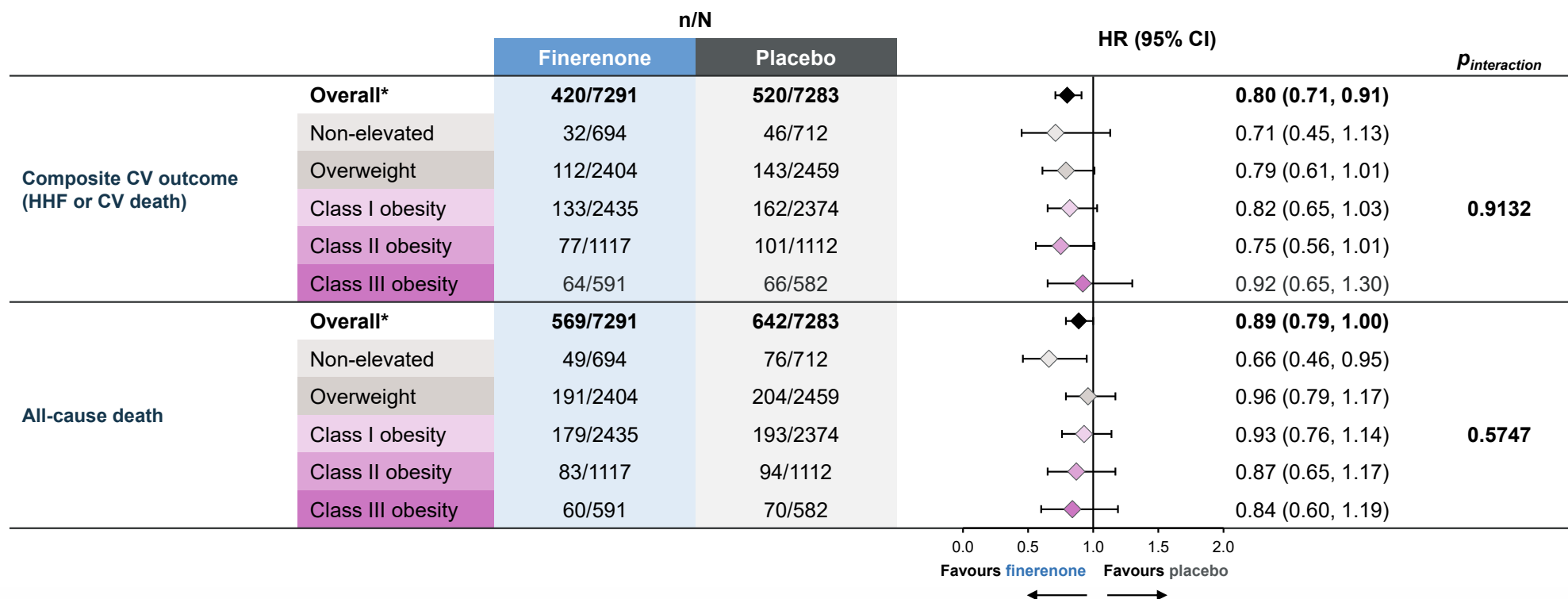
Analysis performed using Cox proportional-hazards models stratified by baseline SGLT2 inhibitor use, screening UACR category and trial with covariates age, sex, pooled race, region, baseline eGFR and log-transformed baseline UACR
 *Defined as sustained eGFR ≤15 ml/min/1.73 m², initiation of dialysis or kidney transplantation. #From baseline for ≥4 weeks. ‡Reported for the total INFINITY population (including participants without a recorded BMI ≥18.5 kg/m²)
 BMI, body mass index; CI, confidence interval; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HHF, hospitalisation for heart failure; HR, hazard ratio; SGLT2, sodium–glucose co-transporter-2; UACR, urine albumin-to-creatinine ratio

Slide 8

MW1 Dear GPC reviewers, just a note to flag that as the models used for this analysis are adjusted, the overall values do not match those in the primary INFINITY publication. The values do not differ by much, but for all cause death the upper CI is now 1.

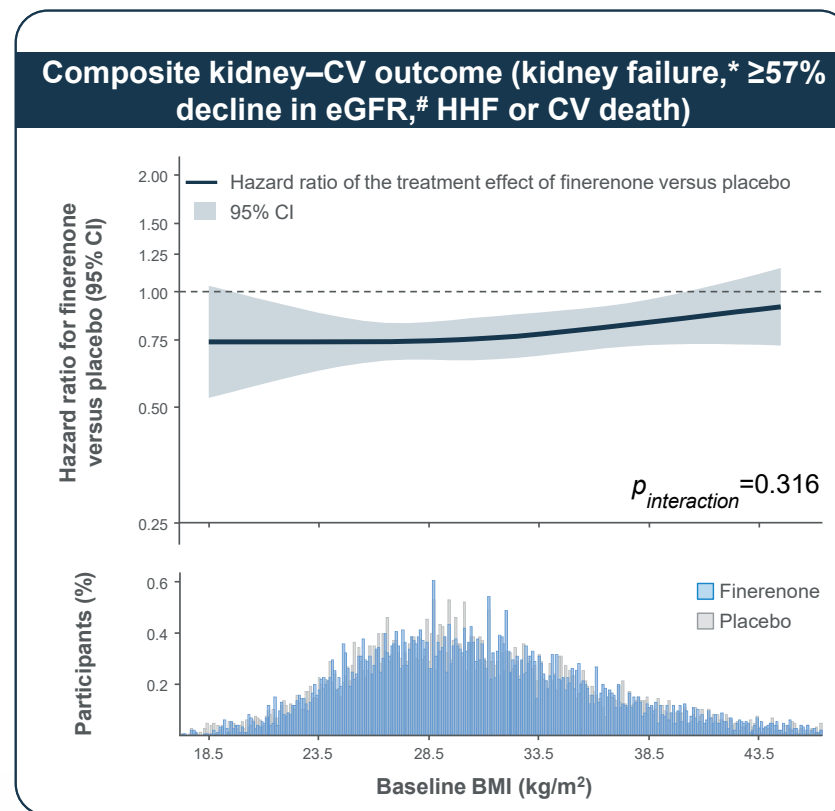
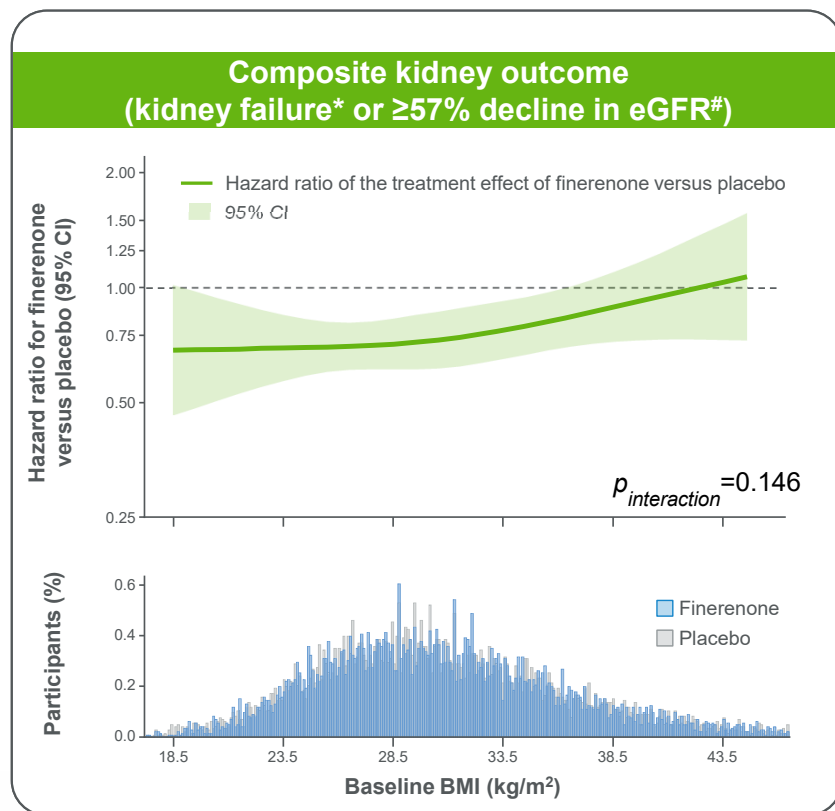
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Impact of baseline BMI category on finerenone efficacy



Analysis performed using Cox proportional-hazards models stratified by baseline SGLT2 inhibitor use, screening UACR category and trial with covariates age, sex, pooled race, region, baseline eGFR and log-transformed baseline UACR
 *Reported for the total INFINITY population (including participants without a recorded BMI ≥ 18.5 kg/m²)
 BMI, body mass index; CI, confidence interval; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HHF, hospitalisation for heart failure; HR, hazard ratio; SGLT2, sodium-glucose co-transporter-2; UACR, urine albumin-to-creatinine ratio

Impact of continuous baseline BMI on finerenone efficacy

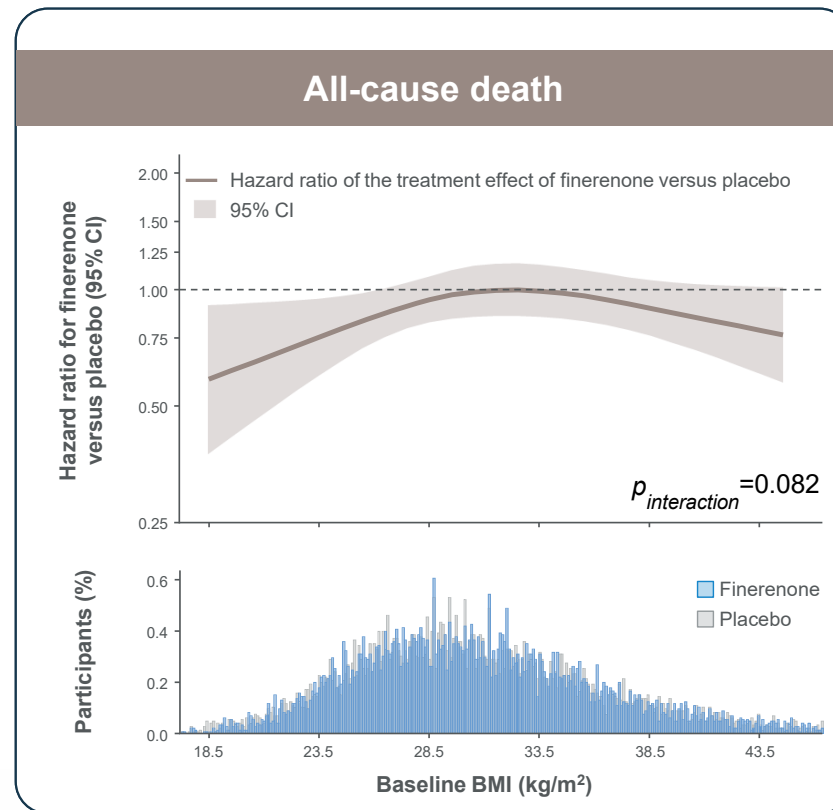
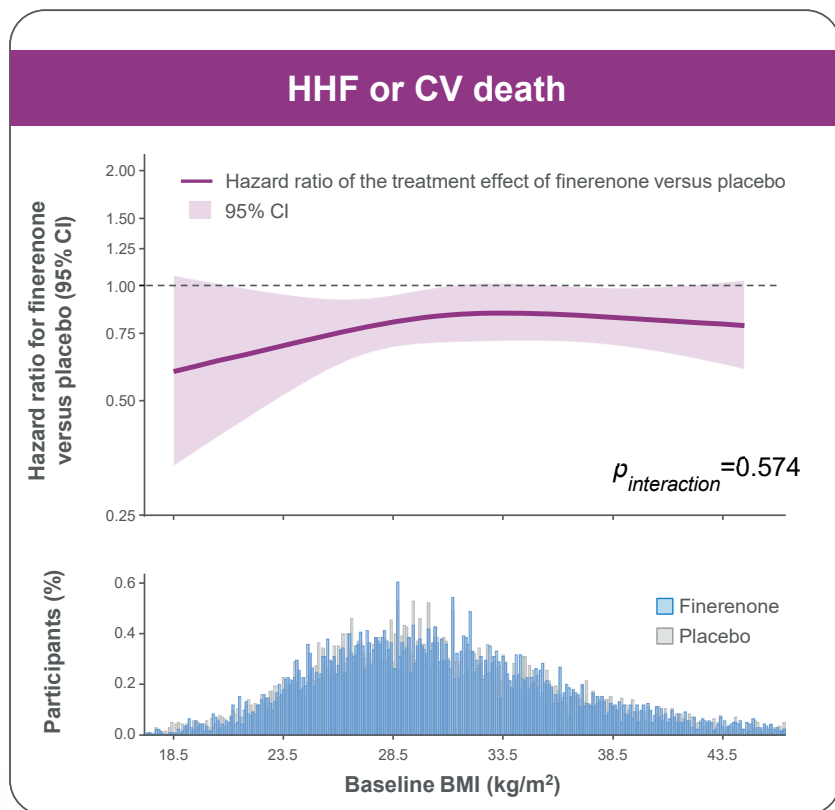


Spline analyses were adjusted for the covariates age, sex, pooled race, region, baseline eGFR and log-transformed baseline UACR

*Defined as sustained eGFR ≤ 15 ml/min/1.73 m², initiation of dialysis or kidney transplantation. #From baseline for ≥ 4 weeks

BMI, body mass index; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HHF, hospitalisation for heart failure; UACR, urine albumin-to-creatinine ratio

Impact of continuous baseline BMI on finerenone efficacy



Spline analyses were adjusted for the covariates age, sex, pooled race, region, baseline eGFR and log-transformed baseline UACR
BMI, body mass index; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HHF, hospitalization for heart failure; UACR, urine albumin-to-creatinine ratio

Treatment-emergent adverse events



Investigator-reported adverse events, n (%)	Non-elevated		Overweight		Class I obesity		Class II obesity		Class III obesity	
	Finerenone (n=694)	Placebo (n=711)	Finerenone (n=2402)	Placebo (n=2452)	Finerenone (n=2434)	Placebo (n=2369)	Finerenone (n=1114)	Placebo (n=1110)	Finerenone (n=590)	Placebo (n=581)
Any adverse event	555 (80.0)	580 (81.6)	2001 (83.3)	2023 (82.5)	2079 (85.4)	2028 (85.6)	947 (85.0)	945 (85.1)	500 (84.7)	505 (86.9)
Leading to treatment discontinuation	31 (4.5)	41 (5.8)	139 (5.8)	131 (5.3)	148 (6.1)	106 (4.5)	67 (6.0)	70 (6.3)	40 (6.8)	24 (4.1)
Any serious adverse event	179 (25.8)	230 (32.3)	710 (29.6)	716 (29.2)	767 (31.5)	763 (32.2)	344 (30.9)	405 (36.5)	204 (34.6)	224 (38.6)
Requiring hospitalisation	170 (24.5)	216 (30.4)	682 (28.4)	678 (27.7)	726 (29.8)	727 (30.7)	338 (30.3)	386 (34.8)	196 (33.2)	217 (37.3)
Leading to treatment discontinuation	4 (0.6)	16 (2.3)	45 (1.9)	59 (2.4)	56 (2.3)	48 (2.0)	23 (2.1)	30 (2.7)	16 (2.7)	8 (1.4)
With fatal outcome	13 (1.9)	17 (2.4)	44 (1.8)	50 (2.0)	38 (1.6)	46 (1.9)	10 (0.9)	24 (2.2)	7 (1.2)	22 (3.8)

Treatment-emergent adverse events: Hyperkalaemia



Investigator-reported adverse events, n (%)	Non-elevated		Overweight		Class I obesity		Class II obesity		Class III obesity	
	Finerenone (n=694)	Placebo (n=711)	Finerenone (n=2402)	Placebo (n=2452)	Finerenone (n=2434)	Placebo (n=2369)	Finerenone (n=1114)	Placebo (n=1110)	Finerenone (n=590)	Placebo (n=581)
Hyperkalaemia*	121 (17.4)	83 (11.7)	357 (14.9)	199 (8.1)	331 (13.6)	167 (7.0)	140 (12.6)	84 (7.6)	85 (14.4)	13 (2.2)
Leading to treatment discontinuation	12 (1.7)	6 (0.8)	42 (1.7)	11 (0.4)	37 (1.5)	12 (0.5)	19 (1.7)	10 (0.9)	11 (1.9)	0
Serious hyperkalaemia	6 (0.9)	4 (0.6)	26 (1.1)	4 (0.2)	20 (0.8)	4 (0.2)	14 (1.3)	7 (0.6)	9 (1.5)	1 (0.2)
Requiring hospitalisation	6 (0.9)	2 (0.3)	24 (1.0)	3 (0.1)	16 (0.7)	4 (0.2)	14 (1.3)	5 (0.5)	7 (1.2)	1 (0.2)
With fatal outcome	0	0	0	0	0	0	0	0	0	0

*Includes events with MedDRA codes "Hyperkalaemia" and "Blood potassium increased"

Conclusions



Higher baseline BMI was associated with a lower risk of kidney disease progression and a higher risk of CV events in participants with CKD



The beneficial effects of finerenone vs placebo on the composite kidney outcome, composite kidney–CV outcome, CV events and all-cause death were consistent across the spectrum of baseline BMI values in this pooled population



Incidence of adverse events and hyperkalaemia adverse events were similar across BMI categories

Hyperkalaemia was more common in the finerenone arm than placebo in all BMI categories, but serious events and events requiring hospitalisation were infrequent