



Impact of finerenone on kidney–cardio outcomes by baseline HbA1c levels in a broad chronic kidney disease population: A pooled analysis (INFINITY)

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Speaker disclosures:

David Z.I. Cherney has received honoraria from Boehringer Ingelheim–Lilly, Merck, AstraZeneca, Sanofi, Mitsubishi-Tanabe, AbbVie, Janssen, Amgen, Bayer, Prometic, Bristol Myers Squibb, Maze, Gilead, CSL Behring, Otsuka, Novartis, Youngene, Lexicon, Inversago, GlaxoSmithKline, Biobridge, Vantage, Altimune and Novo Nordisk; he has also received operational funding for clinical trials from Boehringer Ingelheim–Lilly, Merck, Janssen, Sanofi, AstraZeneca, CSL Behring, Lexicon, Novo Nordisk and Bayer

Background and methods



In **INFINITY**, a pooled analysis of 3 phase III trials including adults with **T2D and CKD** (FIDELIO-DKD and FIGARO-DKD)^{1,2} and **non-diabetic CKD** (FIND-CKD),³ the non-steroidal mineralocorticoid agonist **finerenone** reduced the risk of **kidney disease progression and CV outcomes**⁴



Higher levels of HbA1c, indicative of pre-diabetes or poorly controlled T2D, have been associated with a higher risk of **kidney failure, CV events and death** in these populations⁵⁻⁸



The **aim** of this prespecified analysis was to **investigate the impact of baseline HbA1c levels on the efficacy and safety of finerenone**

Patients from the INFINITY dataset* were stratified by their baseline HbA1c levels into 4 categories:

INFINITY (N=14,574)

R#
1:1

Finerenone 10 or 20 mg[‡] once daily

Placebo

Normoglycaemia (n=958)	<5.7%
Pre-diabetes (n=625)	≥5.7–<6.5%
Adequately controlled T2D (n=8109)	<8.0%
Inadequately controlled T2D (n=4859)	≥8.0%

Includes patients from:



FIND-CKD (N=1584)



FIDELIO-DKD (N=5662)



FIGARO-DKD (N=7328)

Baseline characteristics were generally similar to those reported in the overall INFINITY population⁴

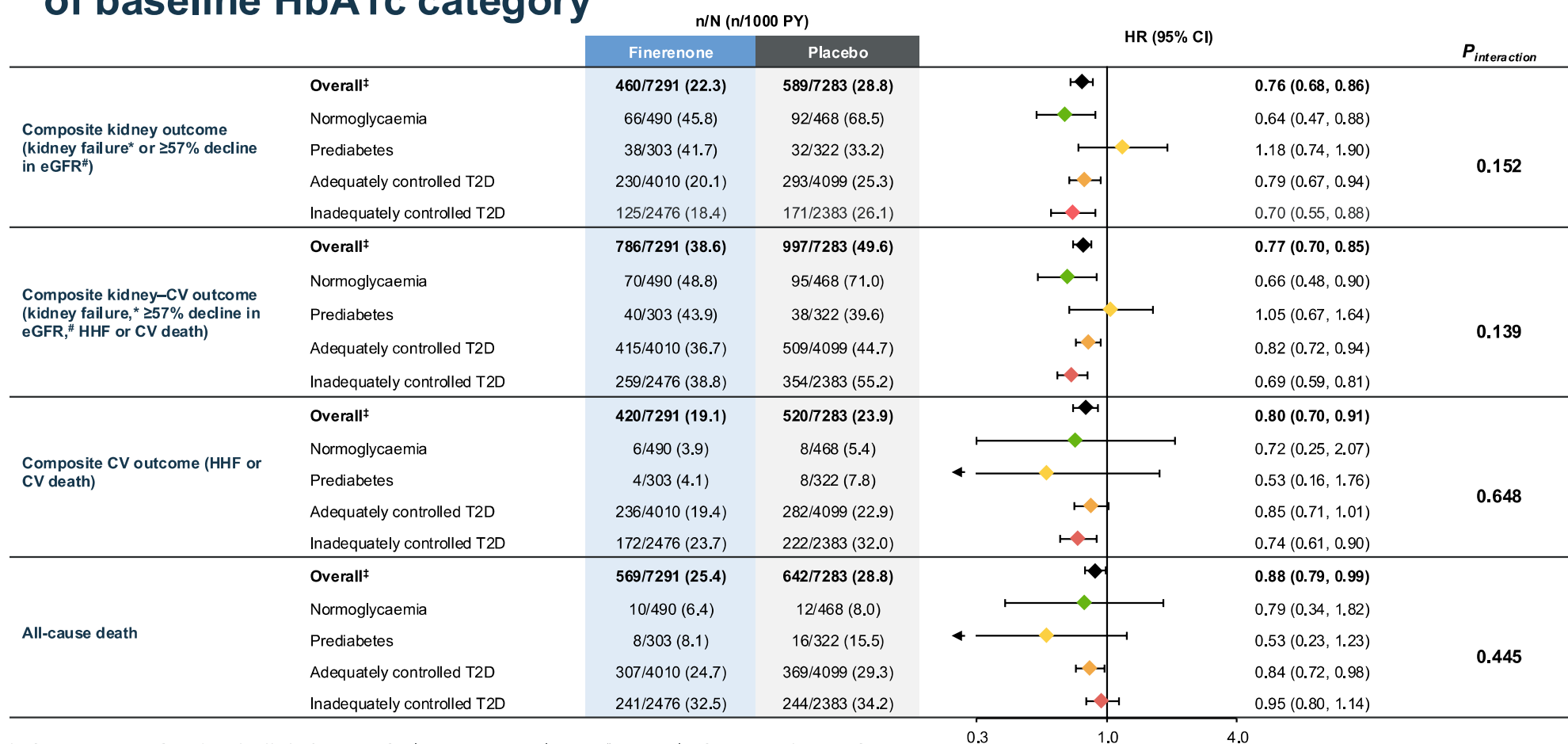
- A higher proportion of patients with normoglycaemia and prediabetes were younger and had a lower mean blood pressure compared with those with T2D
- BMI values increased with baseline HbA1c level

*With an HbA1c measurement at baseline; #Patients were required to be receiving a maximum or stable dose of renin angiotensin system inhibitor for ≥4 weeks before screening; †10 mg for patients 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.

1. Bakris GL, et al. *N Eng J Med*. 2020;383:2219-2229; 2. Pitt B, et al. *N Eng J Med*. 2021;385:2252-2263; 3. Heerspink HJL, et al. *N Eng J Med*. 2026;395:533-545; 4. Neuen BL, et al. *Lancet*. 2026;407:2375-2386; 5. Wan EYF, et al. *BMJ Open Diabetes Res Rev*. 2023;11(1):e003075; 6. Torkamani N, et al. *J Diabetes Complications*. 2020;34:107465; 7. Luk AO, et al. *Diabetes Metab Res Rev*. 2013;29:384-390; 8. Neves JS, et al. *J Clin Endocrinol Metab*. 2020;105:e1772-1780. BMI, body mass index; CKD, chronic kidney disease; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HbA1c, glycated haemoglobin; T2D, type 2 diabetes.

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Finerenone reduced the risk of efficacy outcomes regardless of baseline HbA1c category



*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 23 participants without HbA1c measurements at baseline). CI, confidence interval; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HbA1c, glycated haemoglobin; HHF, hospitalisation for heart failure; HR, hazard ratio; PY, patient-years.

Favours finerenone Favours placebo

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Incidence of hyperkalaemia was similar across baseline HbA1c categories with few events reported as serious or leading to discontinuation



Investigator-reported adverse events, n (%)	Normoglycaemia		Pre-diabetes		Adequately controlled T2D		Inadequately controlled T2D	
	Finerenone (n=490)	Placebo (n=468)	Finerenone (n=303)	Placebo (n=322)	Finerenone (n=4004)	Placebo (n=4091)	Finerenone (n=2474)	Placebo (n=2374)
Any adverse event	339 (69.2)	312 (66.7)	203 (67.0)	204 (63.4)	3451 (86.2)	3555 (86.9)	2124 (85.9)	2030 (85.5)
Adverse events leading to treatment discontinuation	10 (2.0)	15 (3.2)	7 (2.3)	8 (2.5)	265 (6.6)	243 (5.9)	148 (6.0)	106 (4.5)
Any serious adverse event	96 (19.6)	101 (21.6)	70 (23.1)	67 (20.8)	1227 (30.6)	1346 (32.9)	822 (33.2)	832 (35.0)
Requiring hospitalisation	95 (19.4)	94 (20.1)	64 (21.1)	62 (19.3)	1176 (29.4)	1282 (31.3)	788 (31.9)	793 (33.4)
Leading to treatment discontinuation	0	5 (1.1)	1 (0.3)	3 (0.9)	94 (2.3)	105 (2.6)	50 (2.0)	49 (2.1)
With fatal outcome	3 (0.6)	4 (0.9)	3 (1.0)	6 (1.9)	69 (1.7)	88 (2.2)	40 (1.6)	63 (2.7)
Hyperkalaemia*	82 (16.7)	63 (13.5)	53 (17.5)	41 (12.7)	568 (14.2)	278 (6.8)	339 (13.7)	170 (7.2)
Leading to treatment discontinuation	7 (1.4)	1 (0.2)	5 (1.7)	0	67 (1.7)	26 (0.6)	43 (1.7)	12 (0.5)
Serious hyperkalaemia	3 (0.6)	4 (0.9)	5 (1.7)	1 (0.3)	41 (1.0)	6 (0.1)	27 (1.1)	10 (0.4)
Requiring hospitalisation	3 (0.6)	4 (0.9)	4 (1.3)	1 (0.3)	36 (0.9)	3 (0.1)	24 (1.0)	7 (0.3)

*Includes adverse events with the MedDRA codes 10020646 (Hyperkalaemia) and 10005725 (Blood potassium increased).
HbA1c, glycated haemoglobin; T2D, type 2 diabetes.

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Conclusions



In this pre-specified analysis of the INFINITY population, finerenone reduced the risk of kidney and cardiovascular outcomes versus placebo, regardless of baseline HbA1c category



While the incidence of hyperkalaemia was higher with finerenone versus placebo, the incidence of serious hyperkalaemia events was low across HbA1c categories



Together with previous results from the FIND-CKD, FIDELIO-DKD and FIGARO-DKD trials,¹⁻⁴ the present analysis supports the use of finerenone in a diverse clinical profile of adults with CKD across a broad range of metabolic risk

1. Bakris GL, et al. *N Eng J Med.* 2020;383:2219-2229; 2. Pitt B, et al. *N Eng J Med.* 2021;385:2252-2263; 3. McGill JB, et al. *Diabetes Obes Metab.* 2023;25:1512-1522; 4. Heerspink HJL, et al. *N Eng J Med.* 2026;395:533-545.
CKD, chronic kidney disease; HbA1c, glycated haemoglobin.