Supplementary appendix

Supplement to: Agarwal R, Green JB, Heerspink HJL, *et al*. COmbinatioN effect of FInerenone anD EmpagliflοziN in participants with chronic kidney disease and type 2 diabetes using a UACR Endpoint (CONFIDENCE) trial: Baseline clinical characteristics. This appendix has been provided by the authors to give readers additional information about the work.

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Table S1: Study exclusion criteria

Exclusion criteria
• Type 1 diabetes • Known allergies to finerenone or any SGLT2i • Hepatic insufficiency classified as Child–Pugh class C • BP at Day 1 higher than 160 mmHg SBP or 100 mmHg DBP or SBP lower than 90 mmHg • Bilateral clinically relevant kidney artery stenosis (>75%) or other non-diabetic kidney disease • Kidney allograft in place or a scheduled kidney transplant • Experienced AKI within 6 months prior to screening • Experienced ketoacidosis in the past 5 years • Primary adrenal insufficiency (Addison's disease) • Stroke, transient ischaemic cerebral attack, acute coronary syndrome (MI, CABG, primary PCI) or hospitalization for worsening HF within 90 days prior to the screening visit • Clinical diagnosis of chronic HFrEF and persistent symptoms (New York Heart Association class II–IV) at screening visit[a] • Major surgery (major according to the investigator's assessment) performed within 90 days prior to the screening visit, or scheduled major elective surgery (e.g., hip replacement) within 90 days after screening visit • GI surgery or GI disorder that could interfere with absorption of trial medication in the investigator's opinion • Any other history, condition, therapy or uncontrolled intercurrent illness (including AKI) which could in the opinion of the investigator affect participant safety compliance with study requirements • Currently treated with an SGLT2i or SGLT1/2i or have received an SGLT2i or SGLT1/2i that cannot be discontinued at least 8 weeks prior to the screening visit and during study intervention treatment • Treated with strong CYP3A4 inhibitors or inducers that cannot be discontinued 7 days before the Day 1 visit • Treated with another MRA (e.g., eplerenone, esaxerenone, spironolactone, canrenone), a renin inhibitor, potassium supplements, a potassium-sparing diuretic (e.g., amiloride, triamterene), a potassium binder agent, or an angiotensin receptor–neprilysin inhibitor within 8 weeks prior to the screening visit and during study intervention treatment[b] • Currently treated or were treated with finerenone within 8 weeks prior to the screening visit • Participation in another clinical trial with an investigational product within 1 month prior to the screening visit[c] • Serum potassium above 4.8 mmol/L at screening (central laboratory value). Note: One reassessment of serum potassium is allowed at the screening visit • ALT or AST >3× ULN at screening visit • Breastfeeding female participant • Participant known for lack of compliance with clinic visits or prescribed medication

[a] Class 1a recommendation for MRAs

[b] K+ supplements and potassium binder agents will be allowed during the study for safety reasons

[c] Participants who received a COVID-19 vaccine whilst still under Emergency Use Utilization will be eligible, provided vaccination occurred at least 1 month prior to screening visit.

AKI, acute kidney injury; ALT, alanine aminotransferase; AST, aspartate aminotransferase; BP, blood pressure; CABG, coronary artery bypass graft; COVID-19, coronavirus disease 2019; CYP3A4, cytochrome P450 isoenzyme 3A4; DBP, diastolic blood pressure; GI, gastrointestinal; HbA1c, glycated haemoglobin; HF, heart failure; HFrEF, heart failure with reduced ejection fraction; K+, potassium; MI, myocardial infarction; MRA, mineralocorticoid receptor antagonist; PCI, percutaneous coronary intervention; SBP, systolic blood pressure, SGLT1/2i, combined sodium–glucose cotransporter 1 and 2 inhibitor; SGLT2i, sodium–glucose cotransporter 2 inhibitor; ULN, upper limit of normal.

Figure S1: Distribution of KDIGO risk categories stratified by UACR <850 mg/g (A) and ≥850 mg/g (B).

A)

GFR categories (ml/min/1.73 m²)			Albuminuria categories (mg albumin/g creatinine)		
Data presented as *n* (%)			**A1** Normal to mildly increased	**A2** Moderately increased	**A3** Severely increased
			<30[a]	30–300	>300
	G1	≥90	0 (0)	6 (1.2)	13 (2.5)
	G2	60–<90	1 (0.2)	78 (15.0)	94 (18.1)
	G3a	45–<60	0 (0)	46 (8.8)	98 (18.8)
	G3b	30–<45	0 (0)	67 (12.9)	104 (20.0)
	G4	15–<30	1 (0.2)	5 (1.0)	5 (1.0)
	G5	<15	-	-	-

B)

GFR categories (ml/min/1.73 m²)			Albuminuria categories (mg albumin/g creatinine)		
Data presented as *n* (%)			**A1** Normal to mildly increased	**A2** Moderately increased	**A3** Severely increased
			<30	30–300[a]	>300
	G1	≥90	0 (0)	0 (0)	8 (2.8)
	G2	60–<90	0 (0)	2 (0.7)	76 (27.0)
	G3a	45–<60	0 (0)	1 (0.4)	85 (30.2)
	G3b	30–<45	0 (0)	1 (0.4)	92 (32.7)
	G4	15–<30	0 (0)	1 (0.4)	15 (5.3)
	G5	<15	-	-	-

[a] Stratification was based on UACR at screening. UACR may have decreased for participants between the screening and randomization visits.

A, albuminuria; CKD, chronic kidney disease; G, grade; GFR, glomerular filtration rate; KDIGO, Kidney Disease: Improving Global Outcomes; UACR, urine albumin-to-creatinine ratio.

SUPPLEMENTARY REFERENCES

1. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2024 clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney Int* 2024;**105**:S117–S314