# Finerenone in patients with stage 1–4 chronic kidney disease and type 2 diabetes: A secondary analysis of heart failure from the FIGARO-DKD trial

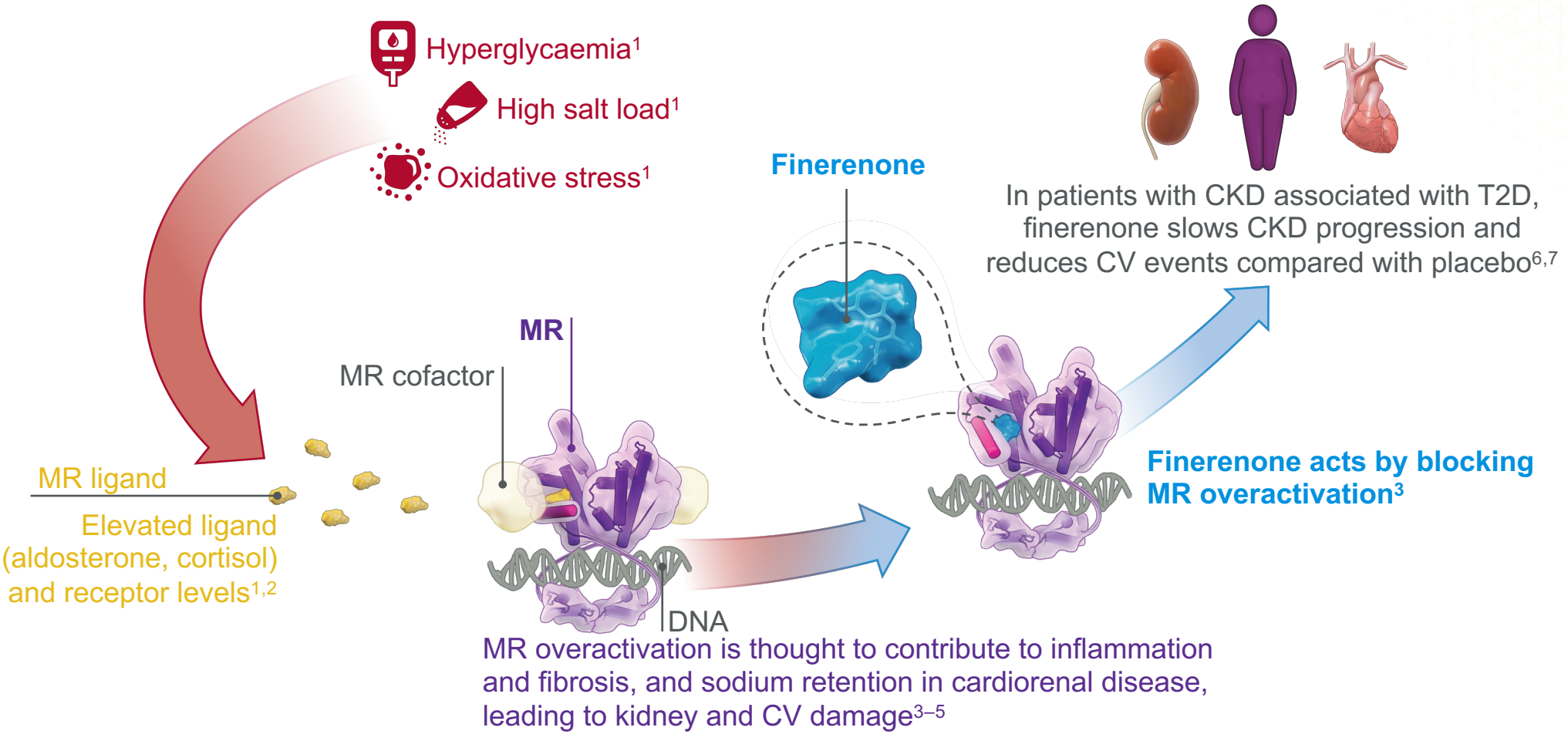
Gerasimos Filippatos, MD, FESC, FHFA, FHFSA(h)

National and Kapodistrian University of Athens

Date of preparation: November 2021
Approval number: MA-M_FIN-ALL-0581

FIGARO-DKD

# Finerenone targets MR overactivation, which contributes to CVD progression in patients with CKD associated with T2D




CKD, chronic kidney disease; CV, cardiovascular; CVD, cardiovascular disease; MR, mineralocorticoid receptor; T2D, type 2 diabetes

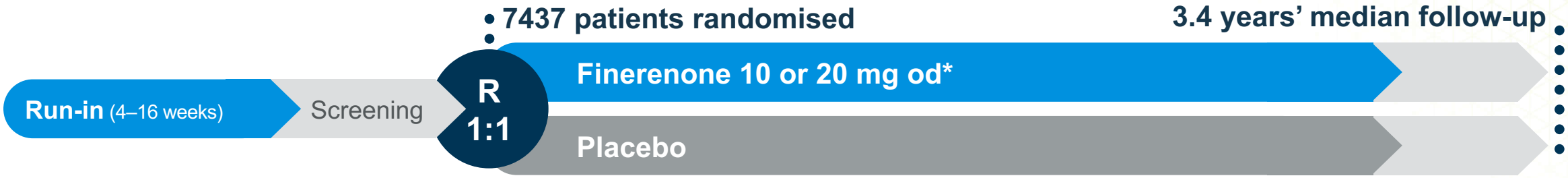
1. Buonafine M, *et al. Am J Hypertens* 2018;31:1165–1174; 2. Buglioni A, *et al. Hypertension* 2015;65:45–53; 3. Agarwal R, *et al. Nephrol Dial Transplant* 2020; doi: 10.1093/ndt/gfaa294; 4. Agarwal R, *et al. Eur Heart J* 2021;42:152–161; 5. Khan NUA & Movahed A. *Rev Cardiovasc Med* 2004;5:71–81; 6. Bakris GL, *et al. N Engl J Med* 2020;383:2219–2229; 7. Pitt B, *et al. N Engl J Med* 2021; doi: 10.1056/NEJMoa2110956.



FIGARO-DKD

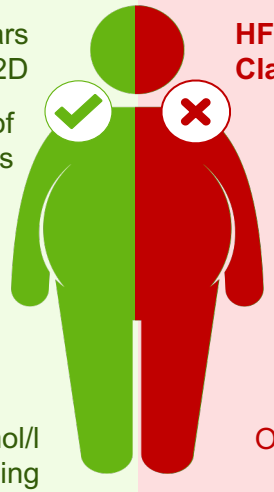
Please note this slide is animated, view in slideshow mode

# FIGARO-DKD was a randomised phase III trial of finerenone vs placebo in patients with early-stage CKD associated with T2D[1]




## Key inclusion criteria

- Aged ≥18 years with T2D
- On max. tolerated dose of ACEi or ARB for ≥4 weeks
- UACR 30–<300 mg/g and eGFR 25–90 ml/min/1.73 m² or UACR 300–5000 mg/g and eGFR ≥60 ml/min/1.73 m²
- Serum [K⁺] ≤4.8 mmol/l at run-in and screening



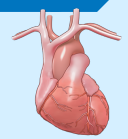
## Key exclusion criteria

- **HFrEF with NYHA Class II–IV**
- Uncontrolled arterial hypertension#
- HbA1c >12%
- Other kidney disease‡

## Key endpoints

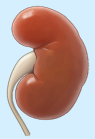
**Primary CV composite**

Time to CV death, non-fatal MI, non-fatal stroke, or HHF



**Secondary kidney composite**

Time to kidney failure, sustained ≥40%/≥57% decrease in eGFR ≥4 weeks from baseline, or renal death



Albuminuria categories[2] (mg albumin/g creatinine)

| GFR categories (ml/min/1.73 m²) | A1 Normal to mildly increased 0–29 | A2 Moderately increased 30–299 | A3 Severely increased ≥300–≤5000 |
|---|---|---|---|
| G1 ≥90 | | | |
| G2 60–89 | | | |
| G3a 45–59 | | | |
| G3b 30–44 | | | |
| G4 15–29 | | | |
| G5 <15 | | | |

*10 mg if screening eGFR <60 ml/min/1.73 m²; 20 mg if ≥60 ml/min/1.73 m², up-titration encouraged from month 1 if serum potassium ≤4.8 mmol/l and eGFR stable; a decrease in the dose from 20 to 10 mg od was allowed any time after the initiation of finerenone or placebo; #mean sitting SBP ≥170 mmHg or mean sitting DBP ≥110 mmHg at the run-in visit, or mean sitting SBP ≥160 mmHg or mean sitting DBP ≥100 mmHg at the screening visit; ‡known significant non-diabetic kidney disease, including clinically relevant renal artery stenosis

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; GFR, glomerular filtration rate; HbA1c, glycated haemoglobin; HFrEF, heart failure with reduced ejection fraction; HHF, hospitalisation for heart failure; [K⁺], potassium concentration; MI, myocardial infarction; NYHA, New York Heart Association; od, once daily; R, randomisation; SBP, systolic blood pressure

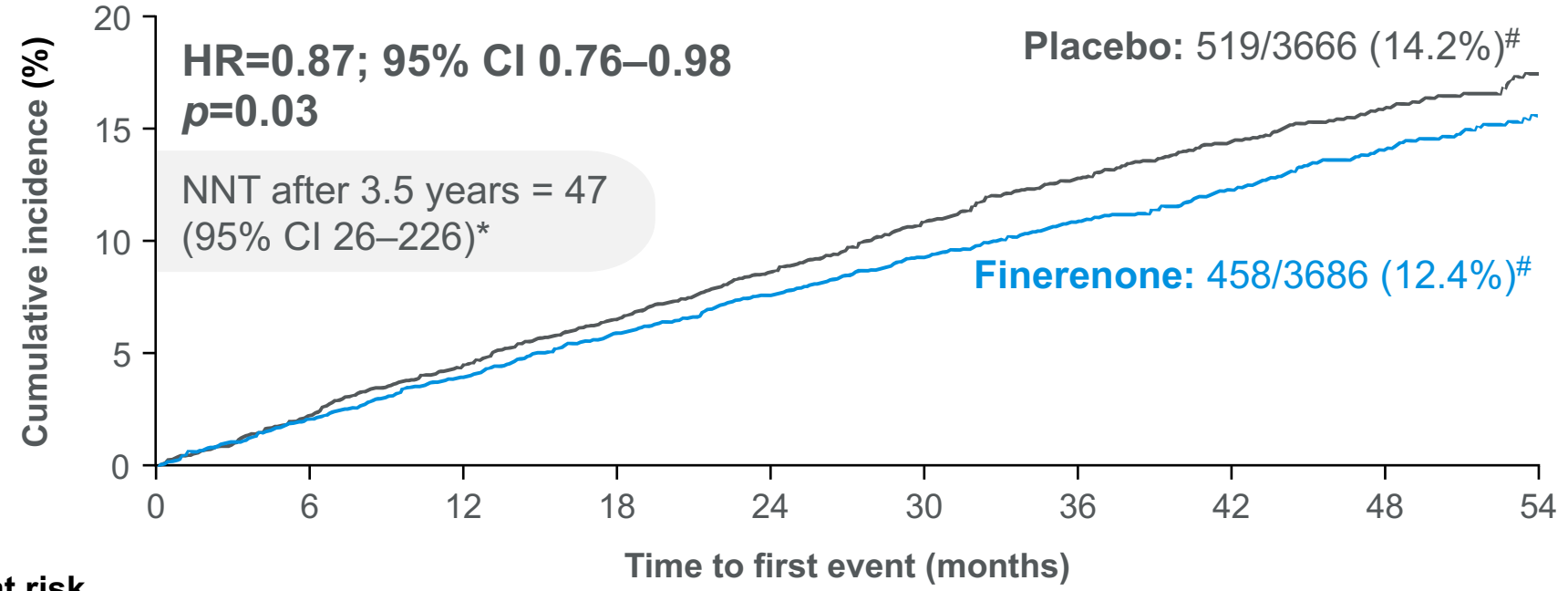
1. Pitt B, *et al. N Engl J Med* 2021; doi: 10.1056/NEJMoa2110956; 2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. *Kidney Int* 2013;3:1–150



FIGARO-DKD

# On top of optimised RAS blockade, finerenone significantly reduced the risk of the primary CV outcome by 13% vs placebo

## Time to CV death, non-fatal MI, non-fatal stroke, or HHF




| No. at risk | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Finerenone | 3686 | 3600 | 3517 | 3427 | 3320 | 2781 | 2184 | 1712 | 1093 | 598 |
| Placebo | 3666 | 3577 | 3479 | 3389 | 3267 | 2730 | 2125 | 1657 | 1076 | 585 |

*NNT calculations based on an absolute risk reduction after 3.5 years of 2.1% (95% CI 0.4–3.8); #number of patients with an event over a median of 3.4 years of follow-up

CI, confidence interval; HR, hazard ratio; NNT, number needed to treat; RAS, renin–angiotensin system

Pitt B, *et al. N Engl J Med* 2021; doi: 10.1056/NEJMoa2110956



FIGARO-DKD

# FIGARO-DKD: A secondary analysis of heart failure

**The aim of this secondary analysis was to evaluate new onset of HF and HF outcomes for patients with and without a history of HF**



Filippatos G, *et al*. *AHA* 2021; abstract 17138

# Patients with a history of HF had lower eGFR and were more likely to have a history of CVD

| Patient characteristic* | With history of HF n=571 | Without history of HF n=6781 |
|---|---|---|
| Age, years | 65.6 | 64.0 |
| Sex, male, % | 61.3 | 70.1 |
| Duration of diabetes, years | 15.1 | 14.4 |
| BMI, kg/m$^2$ | 32.8 | 31.3 |
| SBP/DBP, mmHg | 135/77 | 136/77 |
| HbA1c, % | 8.0 | 7.7 |
| **eGFR, ml/min/1.73 m$^2$** ≥60 ml/min/1.73 m$^2$, % | 52.0 | 62.6 |
| **UACR, mg/g, median** ≥300 mg/g, % | 46.4 | 51.1 |
| **History of CV disease**,# % | 68.7 | 43.3 |
| Serum [K$^+$], mmol/l | 4.4 | 4.3 |

| Medication use, % | With history of HF n=571 | Without history of HF n=6781 |
|---|---|---|
| ACEi | 52.0 | 41.9 |
| ARB | 47.8 | 58.1 |
| Beta blockers | 71.1 | 46.2 |
| Diuretics | 63.6 | 46.2 |
| Statins | 72.5 | 70.3 |
| **Glucose-lowering therapies** | | |
| Metformin | 59.2 | 69.7 |
| Insulin and analogues | 63.6 | 53.5 |
| DPP-4 inhibitors | 17.0 | 24.5 |
| GLP-1RA | 4.2 | 7.8 |
| SGLT-2 inhibitors | 5.6 | 8.6 |

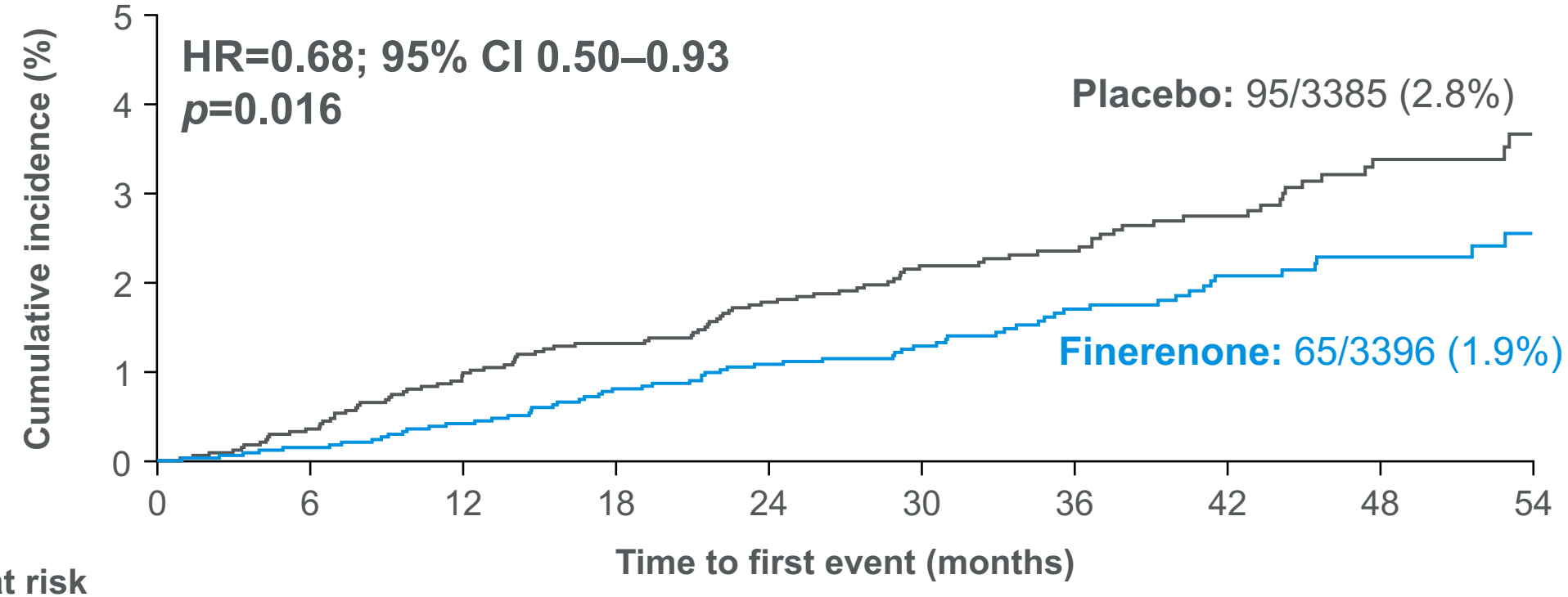
*Values are mean unless otherwise stated; #history of CVD defined as investigator-reported medical history of CAD (coronary revascularisation, or angiography-proven stenosis ≥50% in at least one major coronary artery), ischaemic stroke or PAD
BMI, body mass index; CAD, coronary artery disease; DPP-4, dipeptidyl peptidase-4; GLP-1RA, glucagon-like peptide-1 receptor agonist; HF, heart failure; PAD, peripheral artery disease; SGLT-2i, sodium-glucose co-transporter-2 inhibitor


Filippatos G, *et al*. *AHA* 2021; abstract 17138

FIGARO-DKD

# On top of optimised RAS blockade, finerenone significantly reduced the risk of new-onset HF by 32%

## Finerenone reduced new-onset HF in patients without a history of HF at baseline by 32%




| No. at risk | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Finerenone | 3396 | 3367 | 3323 | 3274 | 3195 | 2710 | 2168 | 1705 | 1091 | 608 |
| Placebo | 3385 | 3351 | 3294 | 3236 | 3154 | 2694 | 2131 | 1674 | 1091 | 606 |

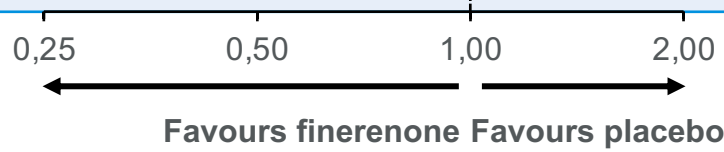


Filippatos G, *et al*. *AHA* 2021; abstract 17138

FIGARO-DKD

# Finerenone reduced CV death and first hospitalisation for HF vs placebo irrespective of history of HF

| First HHF* outcomes | Finerenone n/100 PY | Placebo n/100 PY | Hazard ratio (95% CI) | *p*-value for interaction |
|---|---|---|---|---|
| **CV death and first HHF** | **2.38** | **2.92** | **0.82 (0.70–0.95)** | |
| With a history of HF | 6.57 | 8.67 | 0.84 (0.58–1.22) | 0.81 |
| Without a history of HF | 2.08 | 2.52 | 0.83 (0.70–0.98) | |
| **CV death for HF and first HHF** | **0.99** | **1.44** | **0.68 (0.54–0.86)** | |
| With a history of HF | 3.65 | 5.61 | 0.70 (0.43–1.13) | 0.82 |
| Without a history of HF | 0.79 | 1.15 | 0.69 (0.53–0.91) | |
| **First HHF** | **0.96** | **1.36** | **0.71 (0.56–0.90)** | |
| With a history of HF | 3.53 | 5.35 | 0.70 (0.43–1.15) | 0.77 |
| Without a history of HF | 0.78 | 1.08 | 0.72 (0.55–0.95) | |




*First hospitalisation for HF defined as first event after randomisation
PY, patient-years
Filippatos G, *et al*. *AHA* 2021; abstract 17138



FIGARO-DKD

# Similarly, finerenone reduced CV death and total hospitalisation for HF vs placebo irrespective of history of HF

| Total HHF outcomes | Finerenone n/100 PY | Placebo n/100 PY | Rate ratio (95% CI) | *p*-value for interaction |
|---|---|---|---|---|
| **CV death and total HHF** | **3.04** | **3.84** | **0.79 (0.66–0.95)** | |
| With a history of HF | 10.24 | 14.09 | 0.76 (0.49–1.19) | 0.72 |
| Without a history of HF | 2.50 | 3.09 | 0.81 (0.67–0.99) | |
| **CV death for HF and total HHF** | **1.55** | **2.21** | **0.70 (0.53–0.93)** | |
| With a history of HF | 6.79 | 10.03 | 0.67 (0.37–1.20) | 0.85 |
| Without a history of HF | 1.15 | 1.63 | 0.71 (0.51–0.97) | |
| **Total HHF** | **1.47** | **2.09** | **0.70 (0.52–0.94)** | |
| With a history of HF | 6.68 | 9.67 | 0.67 (0.37–1.22) | 0.91 |
| Without a history of HF | 1.08 | 1.53 | 0.70 (0.51–0.97) | |




Filippatos G, *et al*. *AHA* 2021; abstract 17138

FIGARO-DKD

# Irrespective of HF history, finerenone increased the incidence of hyperkalaemia, but the clinical impact was minimal

| Treatment-emergent AE,* n (%) | With history of HF | | Without history of HF | |
|---|---|---|---|---|
| | Finerenone (n=289) | Placebo (n=281) | Finerenone (n=3394) | Placebo (n=3377) |
| **Any AE** | **230 (79.6)** | **241 (85.8)** | **2904 (85.6)** | **2888 (85.5)** |
| Leading to discontinuation | 8 (2.8) | 13 (4.6) | 199 (5.9) | 170 (5.0) |
| **Any SAE#** | **100 (34.6)** | **89 (31.7)** | **1058 (31.2)** | **1126 (33.3)** |
| Leading to discontinuation | 3 (1.0) | 3 (1.1) | 67 (2.0) | 73 (2.2) |
| **AE with outcome death** | **6 (2.1)** | **8 (2.8)** | **73 (2.2)** | **92 (2.7)** |
| **Hyperkalaemia‡, n (%)** | | | | |
| **Any AE** | **24 (8.3)** | **13 (4.6)** | **372 (11.0)** | **180 (5.3)** |
| Leading to discontinuation | 1 (0.3) | 2 (0.7) | 45 (1.3) | 11 (0.3) |

*AEs that started or worsened after the first dose of study drug up to 3 days after any temporary or permanent interruption of study drug were considered as treatment-emergent AEs; #SAEs were defined as treatment-emergent events that: (1) resulted in death; (2) were life-threatening; (3) required inpatient hospitalisation (or prolongation of existing hospitalisation); (4) caused persistent or significant disability/incapacity; (5) were congenital abnormalities or birth defects; or (6) were judged by the investigator to be a serious or important medical event; ‡hyperkalaemia refers to MedDRA preferred terms hyperkalaemia and blood potassium increase
AE, adverse event; SAE, serious adverse event



Filippatos G, *et al*. *AHA* 2021; abstract 17138

# FIGARO-DKD secondary analysis of HF: Summary and conclusion

**In patients with CKD stage 1–4 with moderate-to-severely elevated albuminuria (UACR ≥30 mg/g), well-controlled SBP and HbA1c, treated with a maximum tolerated dose of RAS blockade:**

**Finerenone reduced new-onset HF by 32%** (HR 0.68; 95% CI 0.50–0.93)

**Finerenone reduced hospitalisation for HF and CV death** irrespective of **history of heart failure**

**Finerenone** was generally **well tolerated**; as anticipated, the incidence of **hyperkalaemia** was higher with finerenone than placebo, but the **clinical impact was minimal**



Filippatos G, *et al*. *AHA* 2021; abstract 17138

# Finerenone in mild to severe chronic kidney disease and type 2 diabetes: a FIDELITY subgroup analysis in patients with heart failure

[Speaker name]

[Affiliation]

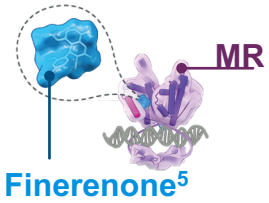
FIDELITY

FInerenone in chronic kiDney diseasE and type 2 diabetes:
Combined FIDELIO-DKD and FIGARO-DKD Trial programme anaYsis

13 November 2021

Approval code: MA-M_FIN-ALL-0582

# Finerenone targets MR overactivation, which may contribute to CV disease progression in patients with CKD associated with T2D




**Finerenone is a novel, selective, nonsteroidal MRA that inhibits MR overactivation, which is thought to contribute to inflammation and fibrosis leading to kidney and CV damage[1–5]**

## FIDELIO-DKD

N=5734

Finerenone reducing **kidney failure and disease progression** in patients with CKD and T2D

**Composite outcome**:[4]
time to onset of kidney failure,* sustained ≥40% decrease in eGFR from baseline, or kidney death
**RRR: 18%**

Same as primary outcome in **FIGARO-DKD**

Primary outcome

Secondary outcome

## FIGARO-DKD

N=7437

Finerenone reducing **cardiovascular mortality and morbidity** in patients with CKD and T2D

**Composite outcome**:[5]
time to CV death, nonfatal MI, nonfatal stroke, or hospitalization for HF
**RRR: 13%**

Same as primary outcome in **FIDELIO-DKD**

*Kidney failure defined as occurrence of ESKD (initiation of chronic dialysis for ≥90 days or kidney transplantation) or sustained eGFR <15 ml/min/1.73 $m^2$

CKD, chronic kidney disease; CV, cardiovascular; eGFR, estimated glomerular filtration rate; ESKD, end-stage kidney disease; HF, heart failure; MI, myocardial infarction; MR, mineralocorticoid receptor; MRA, mineralocorticoid receptor antagonist; RRR, relative risk reduction; T2D, type 2 diabetes

1. Agarwal R, *et al. Nephrol Dial Transplant* 2020; doi: 10.1093/ndt/gfaa294; 2. Agarwal R, *et al. Eur Heart J* 2021;42:152–161; 3. Khan NUA & Movahed A. *Rev Cardiovasc Med* 2004;5:71–81; 4. Bakris GL, *et al. N Engl J Med* 2020;383;2219–2229; 5. Pitt B, *et al. N Engl J Med* 2021; doi: 10.1056/NEJMoa2110956



FIDELITY

# FIDELITY is a prespecified pooled analysis of FIDELIO-DKD[1] and FIGARO-DKD[2]

**13,171 patients randomised**

**3 years' median follow-up**

**48 countries**

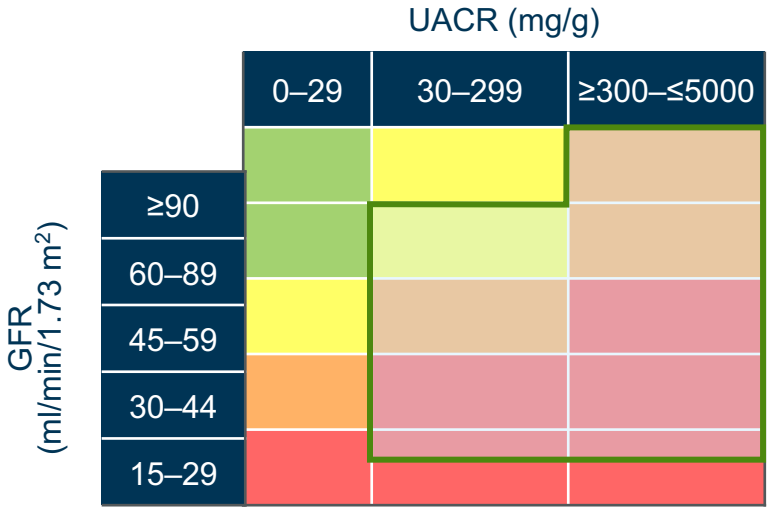
R

Finerenone 10 or 20 mg od*

Placebo

## Key eligibility criteria

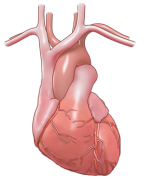
- ✓ **T2D**
- ✓ **CKD**
- ✓ On single RASi
- ✓ Serum [$K^+$] ≤4.8 mmol/l
- ✗ Symptomatic HFrEF




## Key outcomes

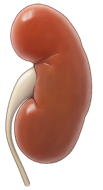
### CV composite

Time to CV death, non-fatal MI, non-fatal stroke, or HHF



### ≥57% eGFR kidney composite

Time to kidney failure#, sustained ≥57% decrease in eGFR from baseline, or renal death



*10 mg if screening eGFR 25–<60 ml/min/1.73 m²; 20 mg if ≥60 ml/min/1.73 m², up-titration encouraged from month 1 if serum [$K^+$] ≤4.8 mEq/l and eGFR stable; #kidney failure defined as either ESKD (initiation of chronic dialysis for ≥90 days or kidney transplant) or sustained decrease in eGFR <15 ml/min/1.73 m²

GFR, glomerular filtration rate; HHF, hospitalisation for heart failure; HFrEF, heart failure with reduced ejection fraction; [$K^+$], potassium concentration; od, once daily; RASi, renin–angiotensin system inhibitor



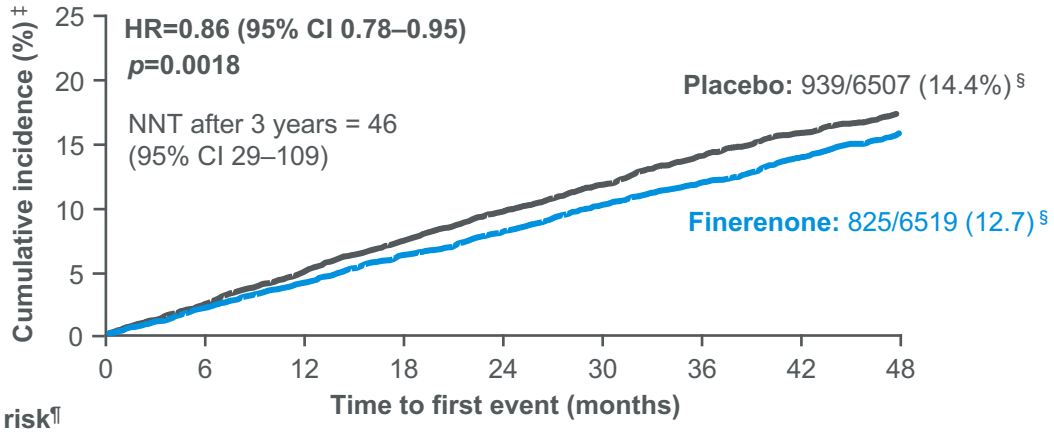
1. Bakris GB, et al. *N Engl J Med* 2020;383:2219–2229; 2. Pitt B, et al. *N Engl J Med* 2021; doi: 10.1056/NEJMoa2110956

FIDELITY

# FIDELITY results overview

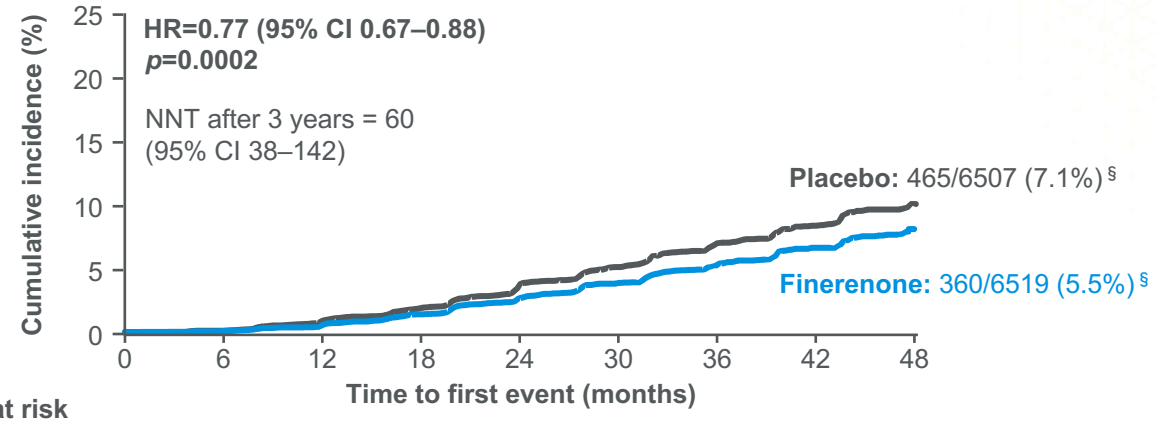
To evaluate the **efficacy and safety of finerenone across the spectrum** of patients with CKD associated with T2D and to provide insights into the relationship between CKD stage and the **effects of finerenone on composite cardiovascular- and kidney-specific endpoints**

**Time to CV death, non-fatal MI, non-fatal stroke, or hospitalisation for HF**




| No. at risk¶ | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Finerenone | 6519 | 6360 | 6202 | 6009 | 5273 | 4207 | 3065 | 2187 | 1087 |
| Placebo | 6507 | 6330 | 6125 | 5938 | 5184 | 4147 | 2969 | 2135 | 1082 |

**Time to kidney failure,* sustained ≥57% decrease in eGFR from baseline, or renal death#**




| No. at risk | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Finerenone | 6519 | 6291 | 6107 | 5848 | 5027 | 3973 | 2815 | 2024 | 959 |
| Placebo | 6507 | 6292 | 6071 | 5815 | 4949 | 3932 | 2798 | 1988 | 962 |

**FIDELITY** showed significant **risk reductions** of **14%** in the **risk of CV morbidity and mortality** vs placebo (HR=0.86; 95% CI 0.78–0.95) and **23%** reduction in the **risk of CKD progression#** vs placebo (HR=0.77; 95% CI 0.67–0.88)[1]

*ESKD or an eGFR <15 ml/min/1.73 $m^2$; #events were classified as renal death if: (1) the patient died; (2) KRT had not been initiated despite being clinically indicated; and (3) there was no other likely cause of death; ‡cumulative incidence calculated by Aalen–Johansen estimator using deaths due to other causes as competing risk; §number of patients with an event over a median of 3.0 years of follow-up; ¶at-risk subjects were calculated at start of time point
CI, confidence interval; HR hazard ratio; KRT, kidney replacement therapy; NNT, number needed to treat



1. Filippatos G, *et al*. ESC 2021 https://esc365.escardio.org/presentation/238815. Hot Line session 28 August 2021

FIDELITY

# At baseline, patients had well-controlled blood pressure and HbA1c, and CV medications were used by most patients

| Characteristic | Total (n=13,026) |
|---|---|
| Age, years | 65 |
| Male, % | 70 |
| Duration of T2D, years | 15.4 |
| HbA1c, % | 7.7 |
| **SBP/DBP, mmHg** | **137/76** |
| **History of CV disease, n (%)** | **5935 (46)** |
| **History of HF, n %** | **1007 (7.7)** |
| Serum [$K^+$], mmol/l | 4.4 |

| Medications, n (%) | Total (n=13,026) |
|---|---|
| CV medications | |
| **RASi** | **13,003 (100)** |
| **Statins** | **9399 (72)** |
| Beta-blockers | 6504 (50) |
| Calcium antagonists | 7358 (57) |
| Diuretics | 6710 (52) |
| Glucose-lowering therapies | 12,720 (98) |
| Metformin | 7557 (58) |
| Insulin | 7630 (59) |
| **GLP-1RAs** | **944 (7.2)** |
| **SGLT-2is** | **877 (6.7)** |

The aim of this subanalysis was to evaluate the effect of finerenone on HF-related outcomes in FIDELITY in the overall population, and across eGFR and UACR subgroups

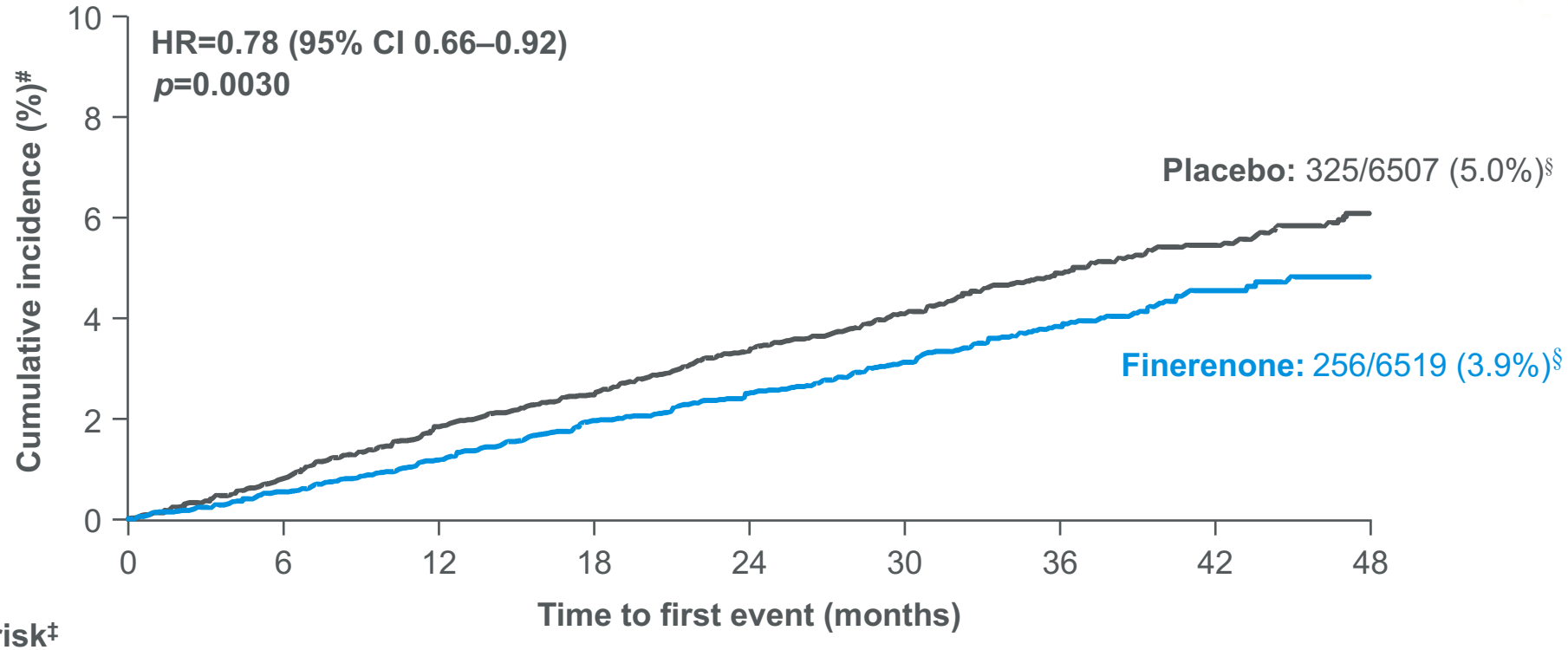
Data are mean unless otherwise stated
DBP, diastolic blood pressure; GLP-1RA, glucagon-like peptide-1 receptor agonist; HbA1c, glycated haemoglobin; SBP, systolic blood pressure; SGLT-2, sodium-glucose co-transporter-2 inhibitor
Filippatos G, *et al*. *AHA* 2021; abstract 17139



FIDELITY

# In FIDELITY, finerenone significantly reduced the risk of first hospitalisation for HF* by 22% vs placebo

## Time to first hospitalisation for HF




| No. at risk‡ | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Finerenone | 6519 | 6431 | 6313 | 6168 | 5450 | 4379 | 3203 | 2299 | 1143 |
| Placebo | 6507 | 6394 | 6246 | 6103 | 5379 | 4342 | 3138 | 2271 | 1144 |

*First hospitalisation for HF defined as first event after randomisation; #cumulative incidence calculated by Aalen–Johansen estimator using deaths due to other causes as competing risk; ‡at-risk subjects were calculated at start of time point; §number of patients with an event over a median of 3.0 years of follow-up

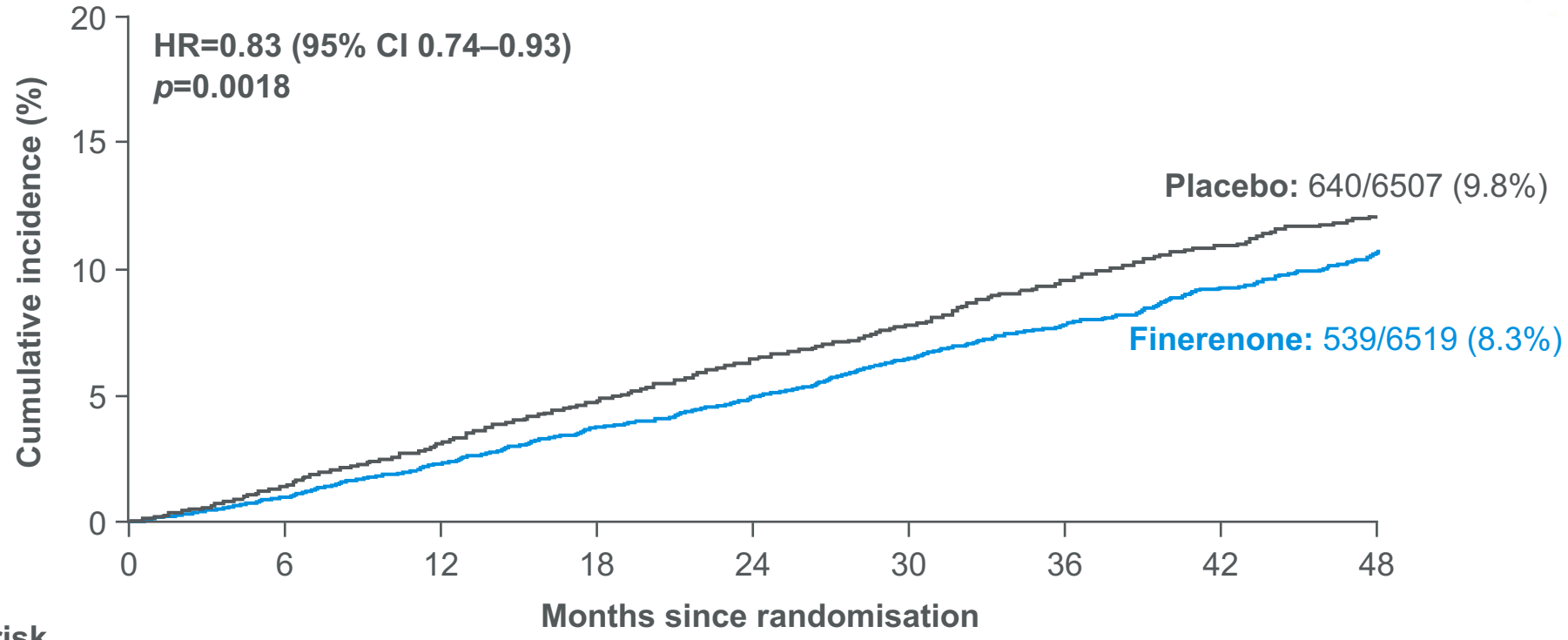
Filippatos G, *et al*. *AHA* 2021; abstract 17139



FIDELITY

# In FIDELITY, finerenone reduced the risk for CV death and first hospitalisation for HF* by 17% vs placebo

## Time to CV death and first hospitalisation for HF




| No. at risk | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Finerenone | 6519 | 6431 | 6313 | 6167 | 5449 | 4379 | 3202 | 2299 | 1143 |
| Placebo | 6507 | 6394 | 6246 | 6102 | 5379 | 4342 | 3138 | 2271 | 1144 |

*First hospitalisation for HF defined as first event after randomisation

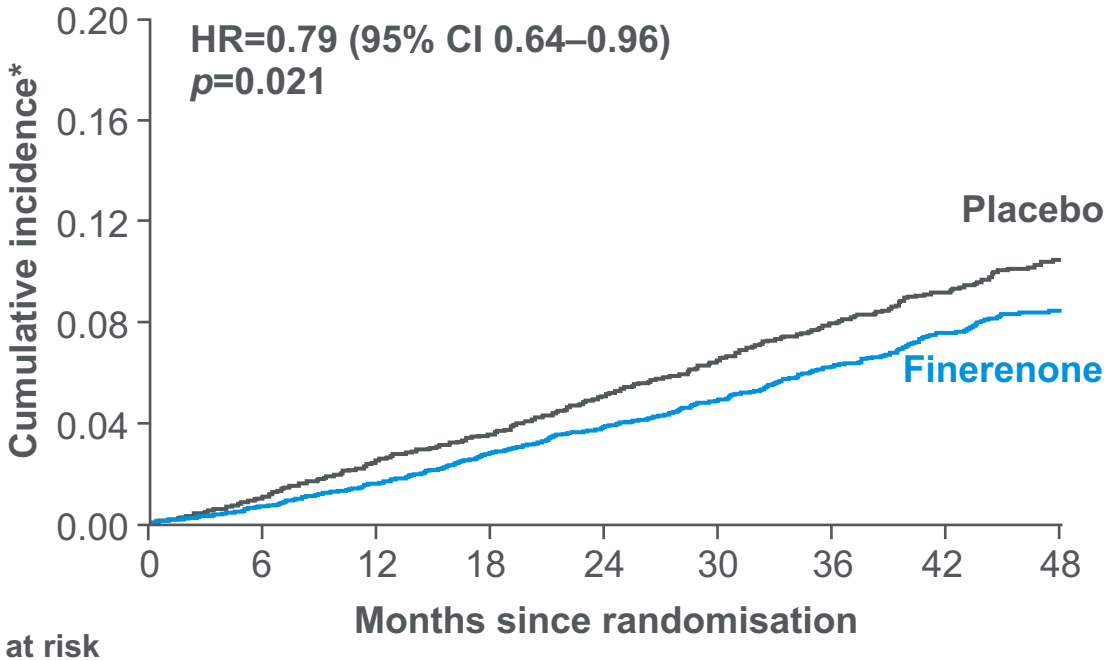


Filippatos G, *et al*. *AHA* 2021; abstract 17139

FIDELITY

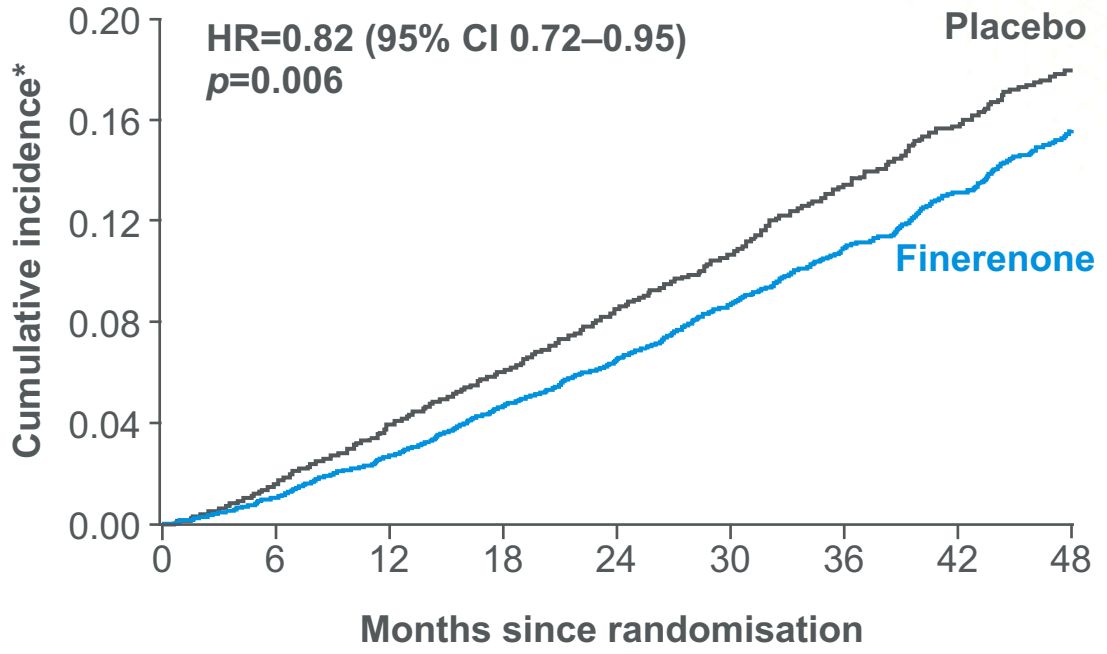
# In FIDELITY, finerenone reduced risk of total hospitalisation for HF and CV death and total hospitalisation for HF

## Time to total HHF (first and recurrent)




| No. at risk | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Finerenone | 6519 | 6464 | 6385 | 6280 | 5573 | 4507 | 3312 | 2395 | 1182 |
| Placebo | 6507 | 6444 | 6351 | 6240 | 5542 | 4495 | 3259 | 2364 | 1184 |

## Time to CV death and total HHF (first and recurrent)




| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 6519 | 6464 | 6385 | 6280 | 5573 | 4507 | 3312 | 2395 | 1182 |
| | 6507 | 6444 | 6351 | 6240 | 5542 | 4495 | 3259 | 2364 | 1184 |

*Cumulative incidence based on mean cumulative function



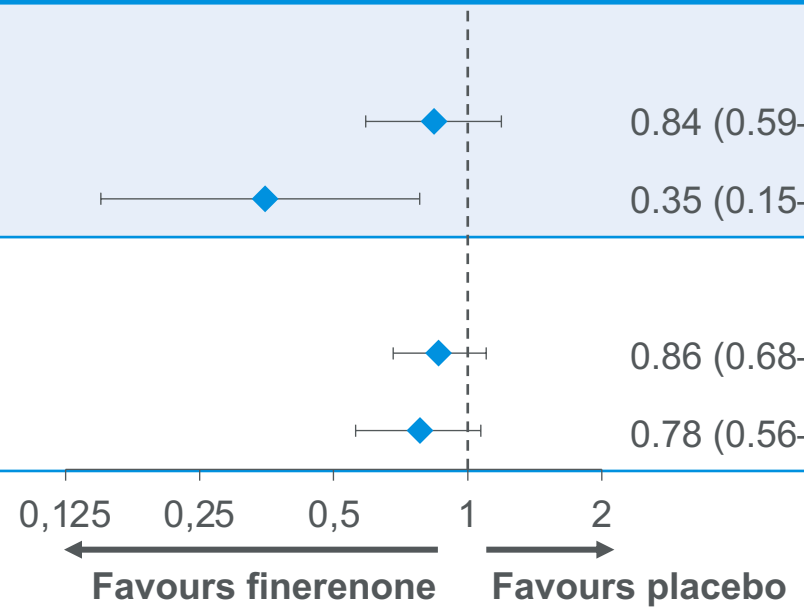
Filippatos G, *et al*. *AHA* 2021; abstract 17139

FIDELITY

# In FIDELITY, finerenone reduced the risk of first hospitalisation for HF vs placebo across the eGFR and UACR spectrum

## Time to first hospitalisation for HF

| Baseline UACR (mg/g) and eGFR (ml/min/1.73 m²) | Finerenone (n=6519) n/100PY | Placebo (n=6507) n/100PY | Hazard ratio (95% CI) | *p*-value for interaction |
|---|---|---|---|---|
| **UACR <300** | | | | |
| eGFR <60 | 1.2 | 1.5 | 0.84 (0.59–1.19) | |
| eGFR ≥60 | 0.4 | 1.0 | 0.35 (0.15–0.78) | |
| **UACR ≥300** | | | | **0.3011*** |
| eGFR <60 | 2.0 | 2.3 | 0.86 (0.68–1.10) | |
| eGFR ≥60 | 1.1 | 1.5 | 0.78 (0.56–1.07) | |




*Typically, a *p*-value <0.1 indicates a statistically significant subgroup effect
UACR, urine albumin-to-creatinine ratio
Filippatos G, *et al*. *AHA* 2021; abstract 17139

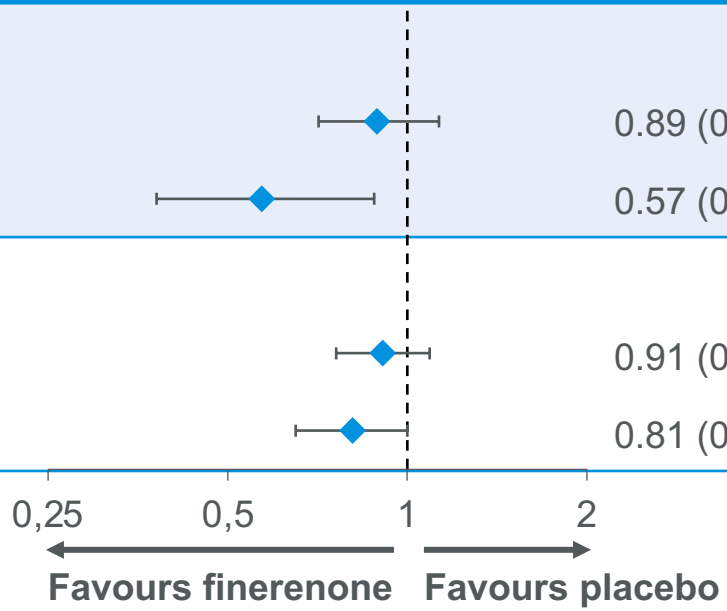


FIDELITY

# In FIDELITY, finerenone also reduced the risk of CV death and first hospitalisation for HF vs placebo across the eGFR and UACR spectrum

## Time to CV death and first hospitalisation for HF

| Baseline UACR (mg/g) and eGFR (ml/min/1.73 m²) | Finerenone (n=6519) n/100PY | Placebo (n=6507) n/100PY | Hazard ratio (95% CI) | *p*-value for interaction |
|---|---|---|---|---|
| **UACR <300** | | | | |
| eGFR <60 | 2.8 | 3.1 | 0.89 (0.71–1.13) | |
| eGFR ≥60 | 1.5 | 2.4 | 0.57 (0.38–0.88) | |
| **UACR ≥300** | | | | 0.3201* |
| eGFR <60 | 3.6 | 4.1 | 0.91 (0.76–1.09) | |
| eGFR ≥60 | 2.4 | 3.0 | 0.81 (0.65–1.00) | |




*Typically, a *p*-value <0.1 indicates a statistically significant subgroup effect



Filippatos G, *et al*. *AHA* 2021; abstract 17139

FIDELITY

# Summary and conclusion

In the FIDELITY prespecified pooled analysis,
in patients with CKD stage 1–4 with moderate-to-severely elevated albuminuria (UACR ≥30 mg/g),
well-controlled SBP and HbA1c, treated with optimised RAS blockade:

**Finerenone reduced the risk of first hospitalization for HF by 22%**
(HR 0.78;
95% CI 0.66–0.92)

**Finerenone reduced the risk of hospitalization for HF and CV death by 17%**
(HR 0.83;
95% CI 0.74–0.93)

**Finerenone reduced hospitalization for HF and CV death, irrespective of eGFR and UACR category**



Filippatos G, *et al*. *AHA* 2021; abstract 17139