



Kerendia (Finerenone) - a new treatment option for CKD with T2D

Investor-Webinar

November 15, 2021

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Agenda

1

Welcome

Oliver Maier

Head of Investor Relations

2

Prepared Remarks



Christian Rommel

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Operations Americas,
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3

Q&A



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The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.



We laid the foundation for long-term growth at Pharma

Main building blocks of post LoE growth

Late-stage Pipeline in CV & WH

 **Verquuvo**¹
(vericiguat) tablets
2.5 mg, 5 mg, 10 mg

PSP ~ €0.5bn



 **Kerendia**[®]
finerenone

PSP ≥ €1.0bn

Elinzanetant
(KaNDy NT-814)


PSP ≥ €1.0bn

Pipeline
(e.g. FXI portfolio, Eliapixant)

Oncology

 **NUBEQA**[®]²
(darolutamide) 300 mg tablets

PSP ≥ €1bn

 **VITRAKVI**[®]
(larotrectinib) 25-mg/100-mg CAPSULES
20-mg/mL ORAL SOLUTION

PSP > €0.75bn

Pipeline
GFRexon20 inhib., ATR
TTCs

Cell & Gene Therapy Platform

C> platform expected to deliver significant sales contributions from ~2025 onwards



External Innovation and BD&L

>25 BD&L-transactions signed in 2020
Enhanced focus on external innovation to replenish pipeline

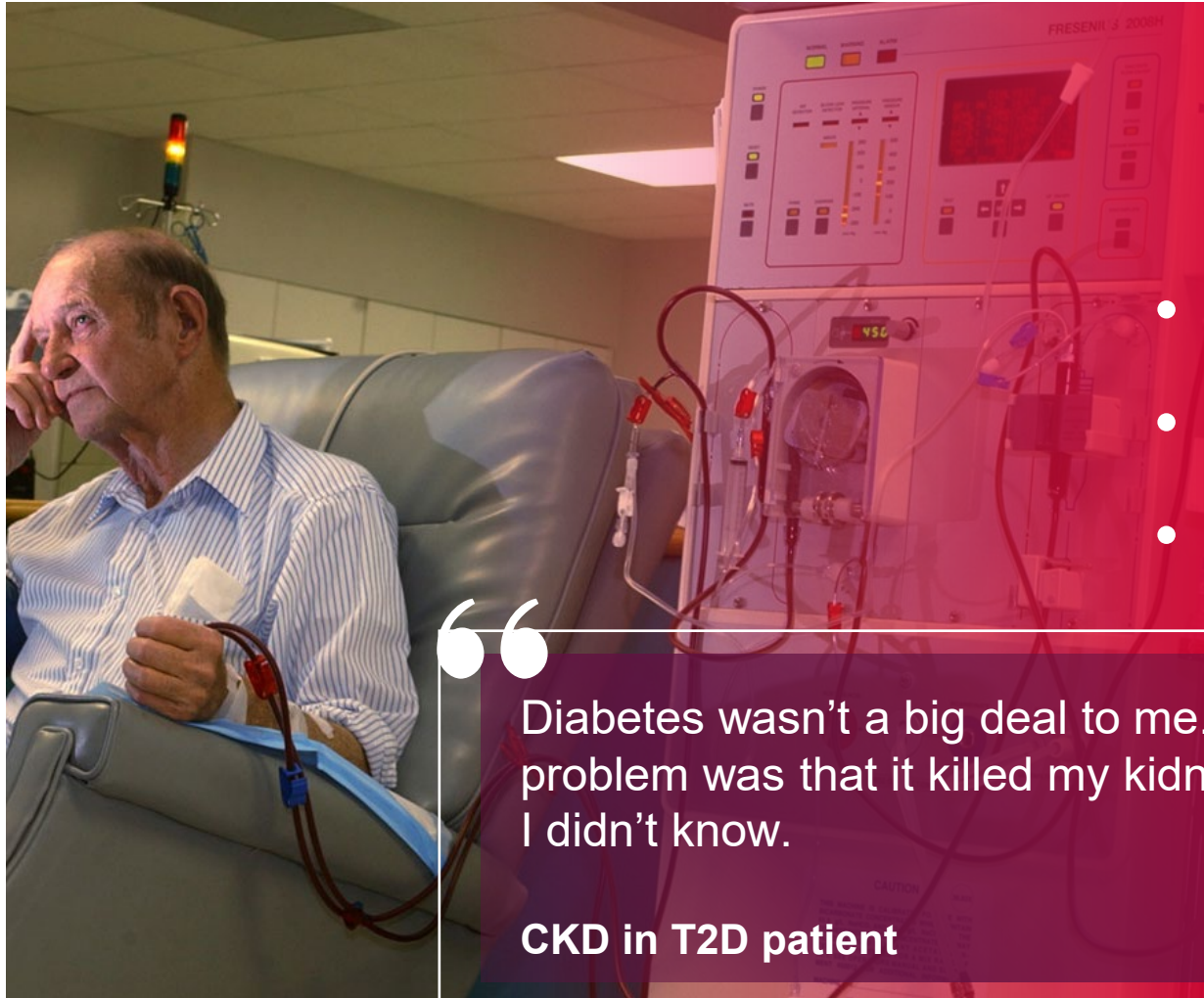


¹ In collaboration with Merck & Co. Inc., Kenilworth, NJ, USA

² In collaboration with Orion Corporation



Kerendia is addressing an area of high unmet medical need



Chronic Kidney Disease in Type-2-Diabetes

- 160 mio patients globally
- Shortens life expectancy by 16 years
- #1 cause for dialysis / transplants

“Diabetes wasn't a big deal to me. The problem was that it killed my kidneys and I didn't know.”

CKD in T2D patient

Alicic RZ, et al. Clin J Am Soc Nephrol. 2017
Wen CP, et al. Kidney Int. 2017
Thomas MC, et al. Nat Rev Dis Primers. 2015
/// Finerenone Investor Webinar /// November 2021



Multiple unmet needs exist in cardio-renal disease

37 Million people in the US estimated to have CKD

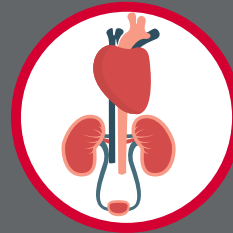
Patient needs

CKD with T2D carries **3x risk of CV death** and **is #1 cause of ESRD**

Over 50% of CKD patients progress to stages 3 & 4

Patients need simple/easy to take medications **with manageable side-effect burden**

CKD with Type-2-Diabetes:
A high-risk population



Insufficient treatment options available

HCP needs

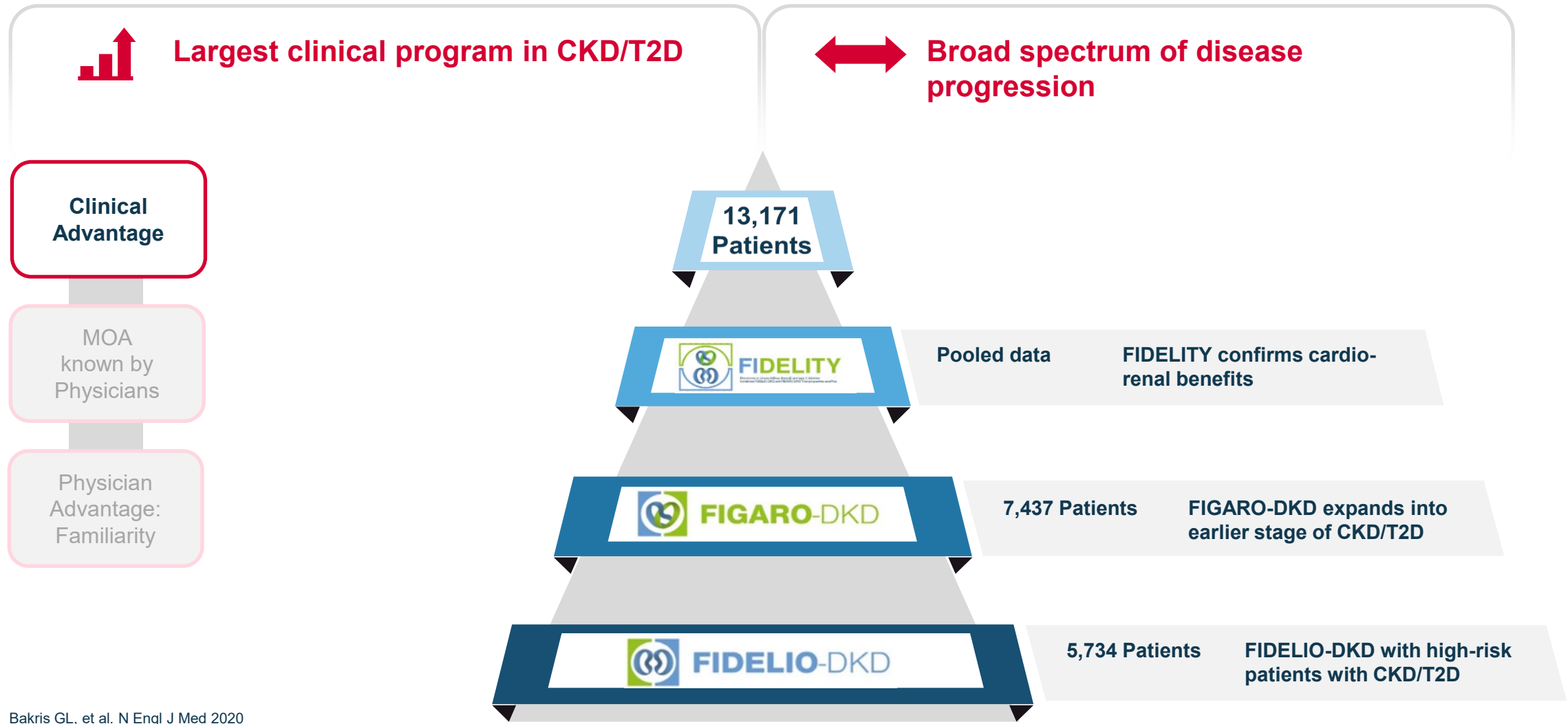
71% of HCP confirm strong unmet need **despite SOC**

~70% of HCPs confirm need to go beyond risk factor management with a **kidney dedicated treatment to delay CKD progression**

Therapeutics with clinical utility **across a broad spectrum of patients**



The Phase III trial program for Finerenone in CKD/T2D yields clinical advantage



Bakris GL, et al. N Engl J Med 2020
Pitt, B., et al. N Engl J Med 2021

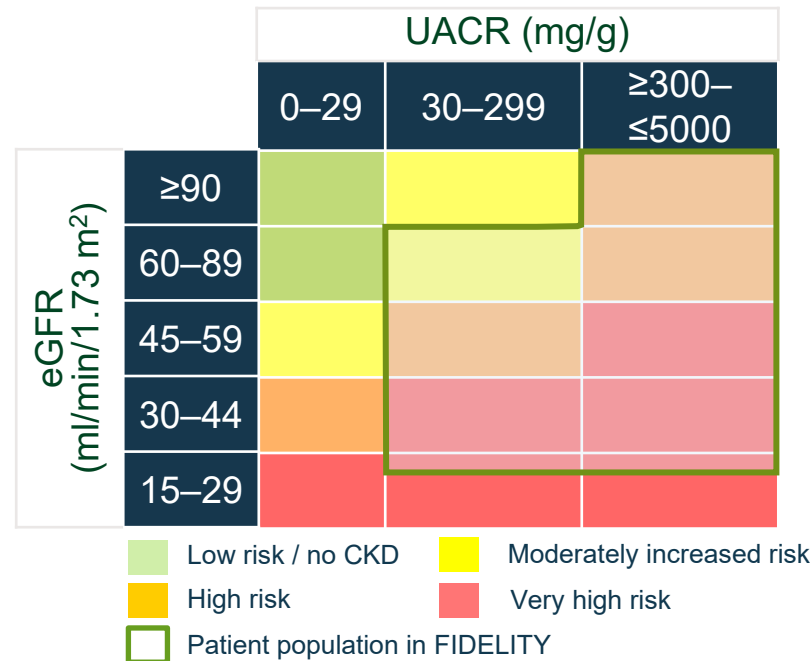


FIDELITY is a large, prespecified pooled analysis of FIDELIO-DKD and FIGARO-DKD

13,171 patients randomized across the CKD/T2D continuum

Key eligibility criteria

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



Broad disease spectrum
Robust data in both early disease and late disease

CV Composite
Time to CV death, non-fatal MI, non-fatal stroke, or hospitalization for HF

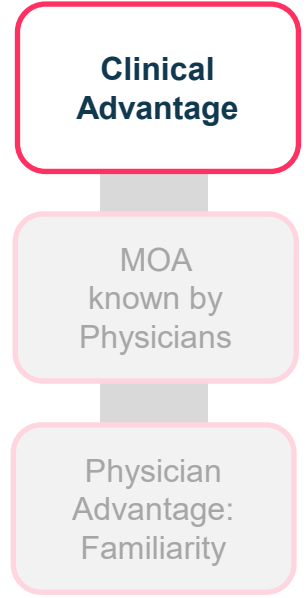
57% eGFR kidney composite
Time to kidney failure, sustained ≥57% decrease in eGFR from baseline, or renal death

General remarks:

- CKD = eGFR <60 ml/min/1.73 m² and/or UACR >30 mg/g for more than 3 months
- Risk of adverse outcomes in patients with CKD/T2D increases as eGFR falls and UACR rises



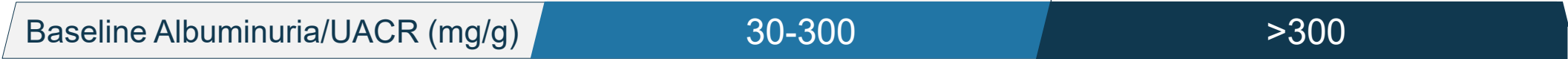
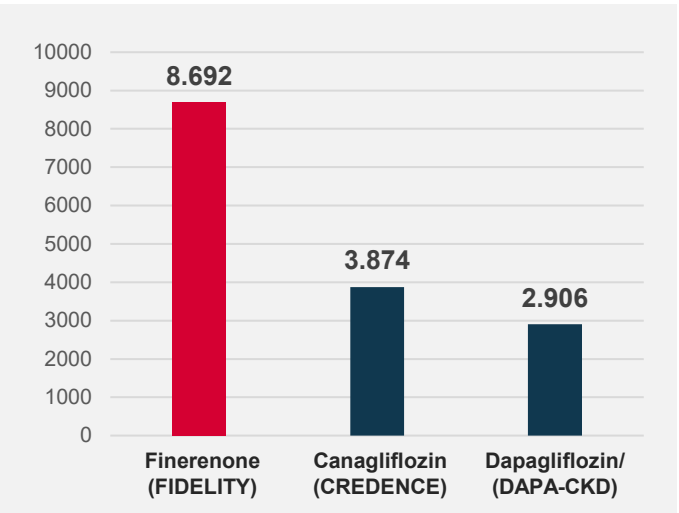
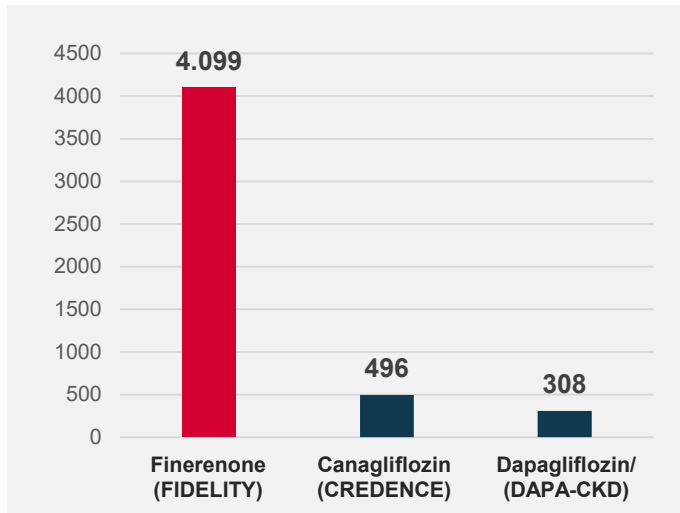
The FIDELITY program for Finerenone enrolled more early-stage patients than other contemporary trials in CKD/T2D



No. of CKD/T2D-patients (Total trial participants)

Robust data in patients EARLY in CKD/T2D progression

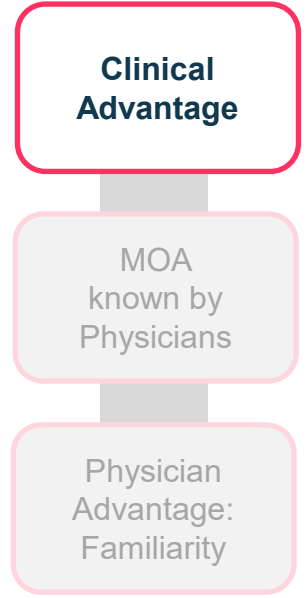
Earlier/broader CKD/T2D patient population than SGLT-2i which were mainly tested in higher-risk/late-stage patients



Perkovic V. et al. . N Engl J Med 2019
 Wheeler DC et al., Nephrol Dial Transplant. 2020
 Agarwal, R. et al., data presented at ESC 2021



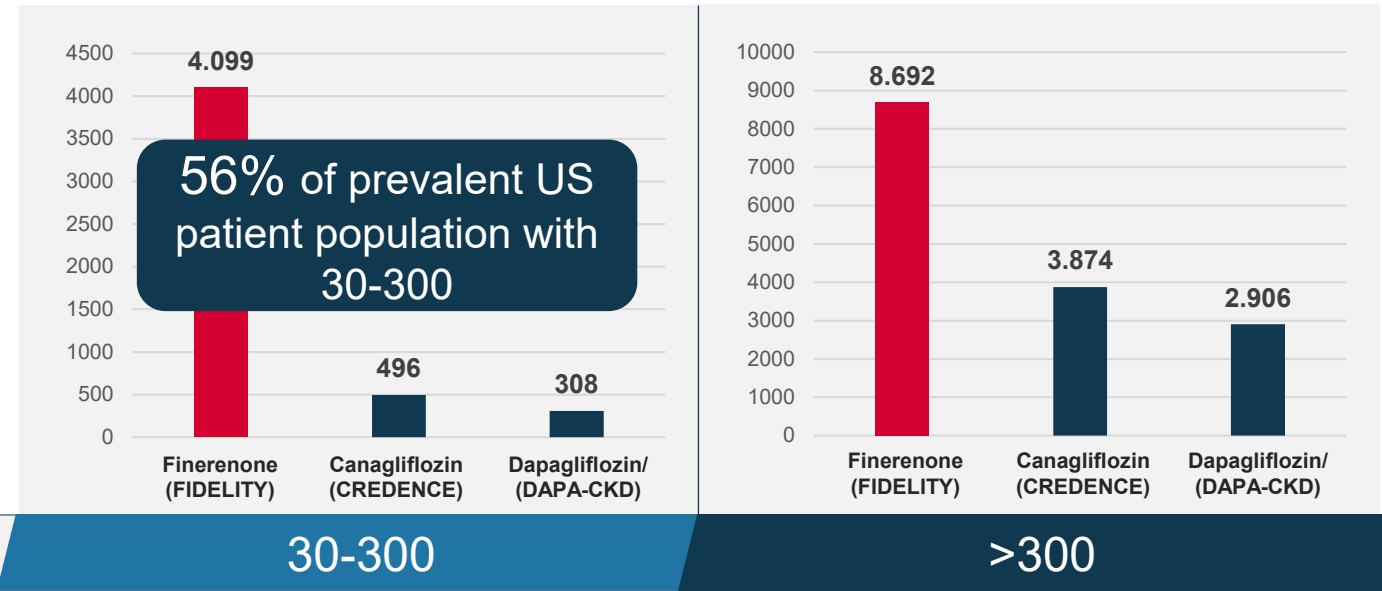
Early-stage patients represent the majority of the prevalent CKD/T2D patient population



No. of CKD/T2D-patients (Total trial participants)

Robust data in patients EARLY in CKD/T2D progression

Earlier/broader CKD/T2D patient population than SGLT-2i which were mainly tested in higher-risk/late-stage patients



Perkovic V. et al. . N Engl J Med 2019
 Wheeler DC et al., Nephrol Dial Transplant. 2020
 Baily R.A. et al, BMC Res Notes 2014
 Agarwal, R. et al., data presented at ESC 2021
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Finerenone provides heart and kidney protection in patients with mild to severe CKD and T2D

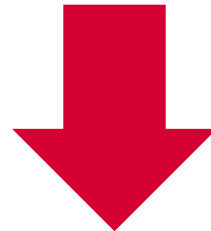
Key results of the FIDELITY pooled analysis



Composite CV Outcome

HR = 0.86
(95% CI 0.78-0.95), $p=0.0018$
NNT 46

Relative risk reduction compared to placebo



-14%



57% eGFR Composite Kidney Outcome

HR = 0.77
(95% CI 0.67-0.88), $p=0.0002$
NNT 59

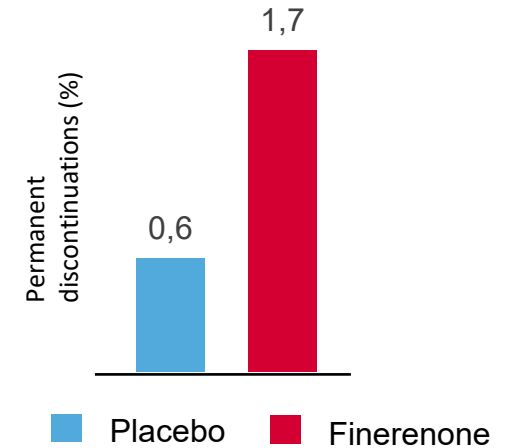
Relative risk reduction compared to placebo



-23%

[K⁺] Hyperkalemia

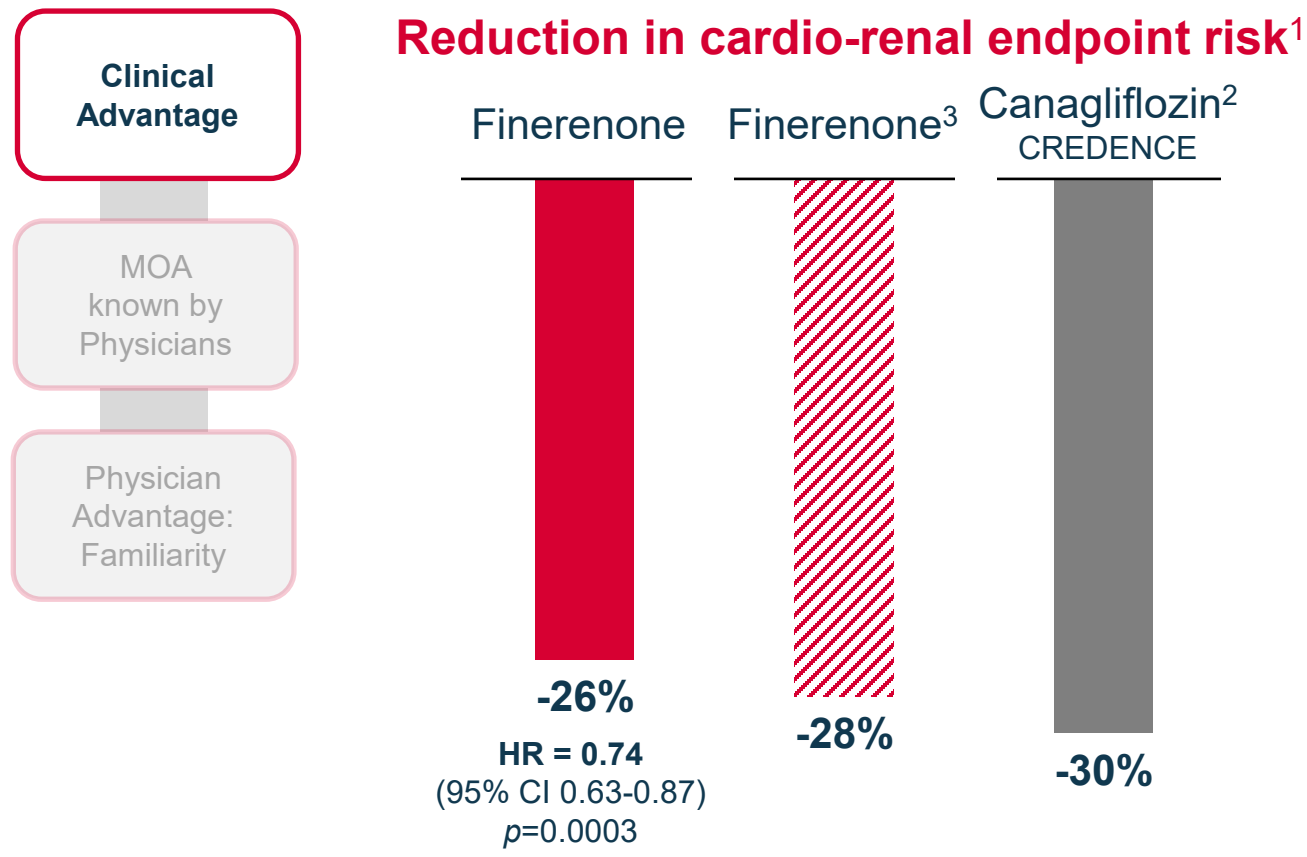
~1% placebo adjusted permanent discontinuations due to hyperkalemia





Finerenone with cardio-renal endpoint risk reduction comparable to Canagliflozin when trial differences are considered

FIDELIO-DKD “CREDESCENCE-like” post-hoc analysis

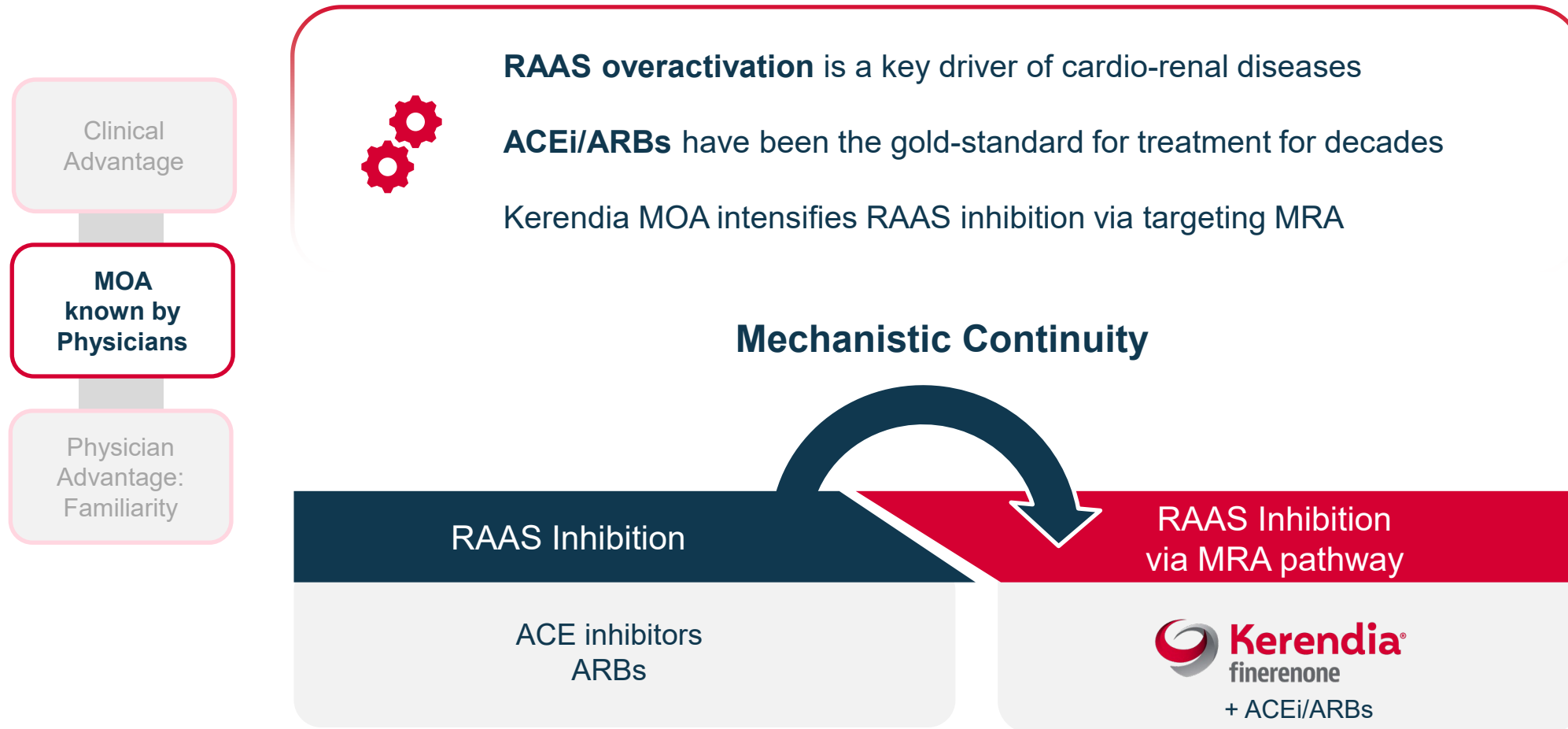


- Post-hoc analysis of FIDELIO-DKD
- Patient inclusion criteria adjusted to those of the CREDESCENCE trial with canagliflozin
 - UACR >300 - 5,000 mg/g
 - eGFR 30 - <90 ml/min/1.73m²
- Cardio-renal endpoint definition equivalent to CREDESCENCE trial
 - Composite of kidney failure, eGFR decrease of >57% from baseline for ≥ 4 weeks or renal or cardiovascular death vs. placebo
- 81% of patients included in FIDELIO-DKD were eligible for analysis

Agarwal R. et al, AHJ (242) 2021
1) No head-to-head trials available
2) Perkovic et al., N Engl J Med (2019)
3) Calculated analysis, adjusted for history of heart failure

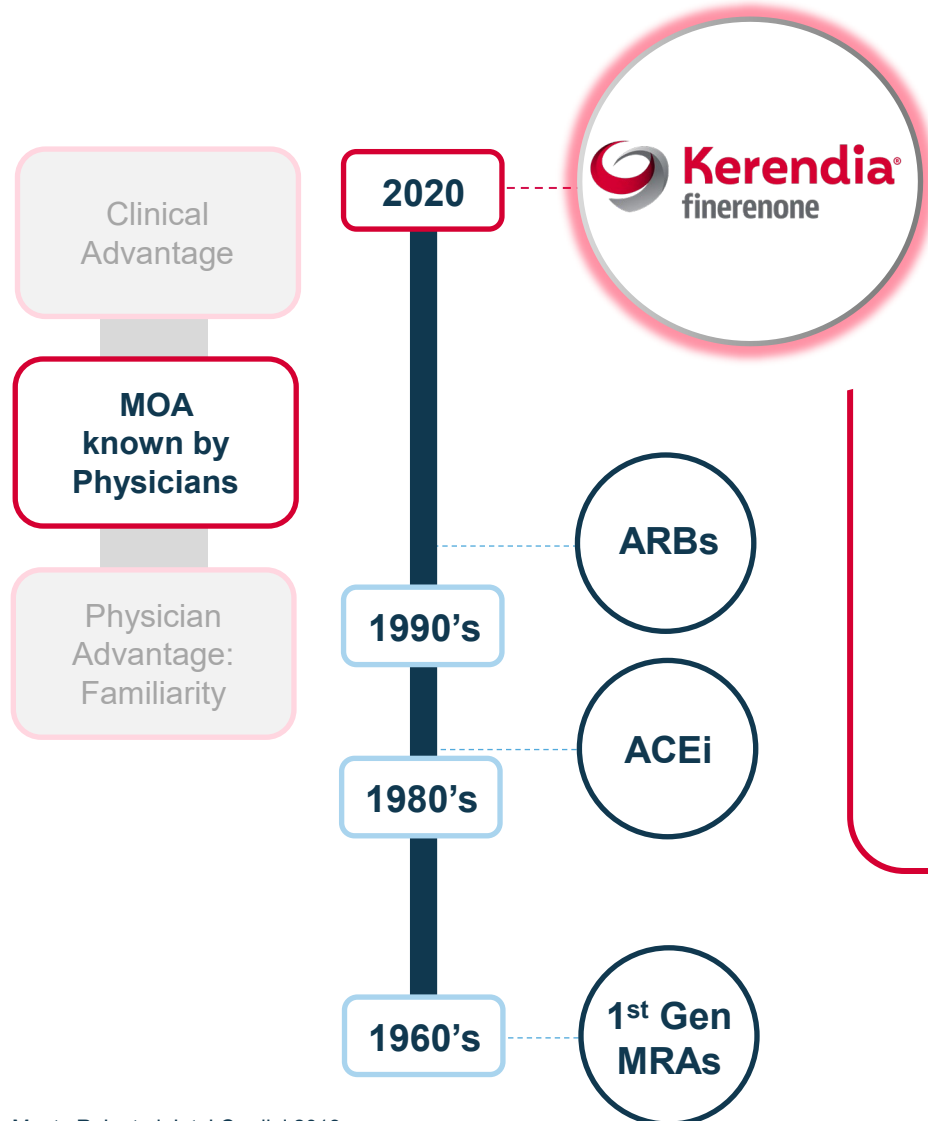


Kerendia provides mechanistical continuity for the treatment of cardio-renal diseases





RAASi-intensification is accomplished with Kerendia on top of ACEi/ARBs

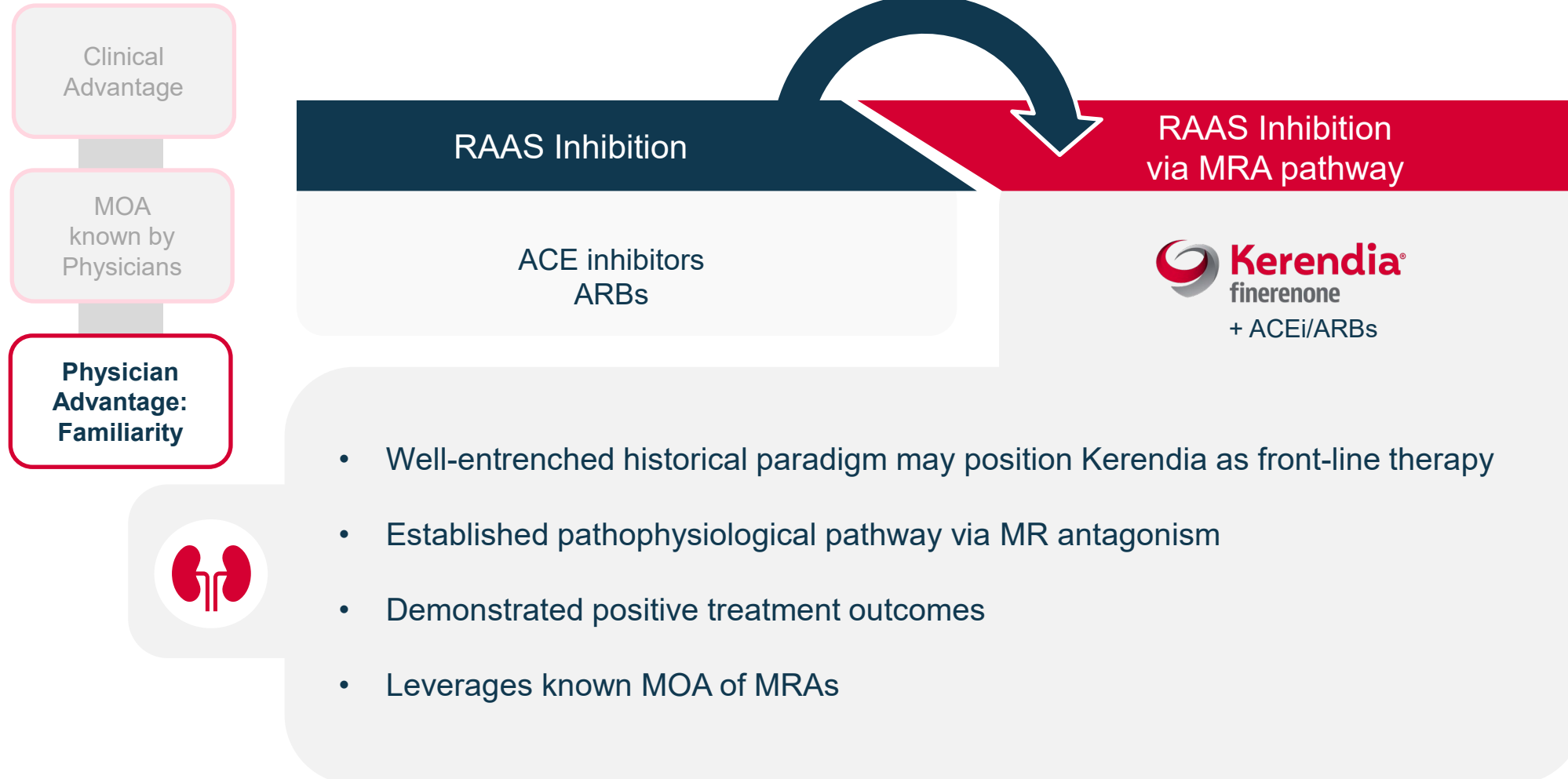


- **In Kerendia – Bayer has accomplished what many have tried and failed to do for the last 25 years**
- **RAASi-intensification through Kerendia continues the long RAAS-centric treatment history**
- **Clinical implications from FIDELITY:**
 - Addresses the unmet need/residual risk for patients
 - Decreases risk without significant increase in overall AE's
 - Manageable hyperkalemia
 - Potential for earlier treatment of CKD/T2D



Kerendia addresses familiarity of physicians with established mode of action

Mechanistic Continuity





FDA approved Kerendia with a broad label recognizing the renal and cardiovascular outcomes in FIDELIO-DKD

US-Indication Indicated to reduce the risk of **sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure** in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

Clinical Data Based on FIDELIO-DKD

Efficacy Full reflection of the main components of the primary renal and the key sec. cardiovascular composite endpoints

Safety Favorable benefit-to-risk ratio with hyperkalemia the only risk factor mentioned in the warnings and precautions section of the US-label



Strong commitment to a broad availability to the cardio-renal potential of Kerendia



Peak sales potential
> EUR 1bn



Launched



Filed 11/2020

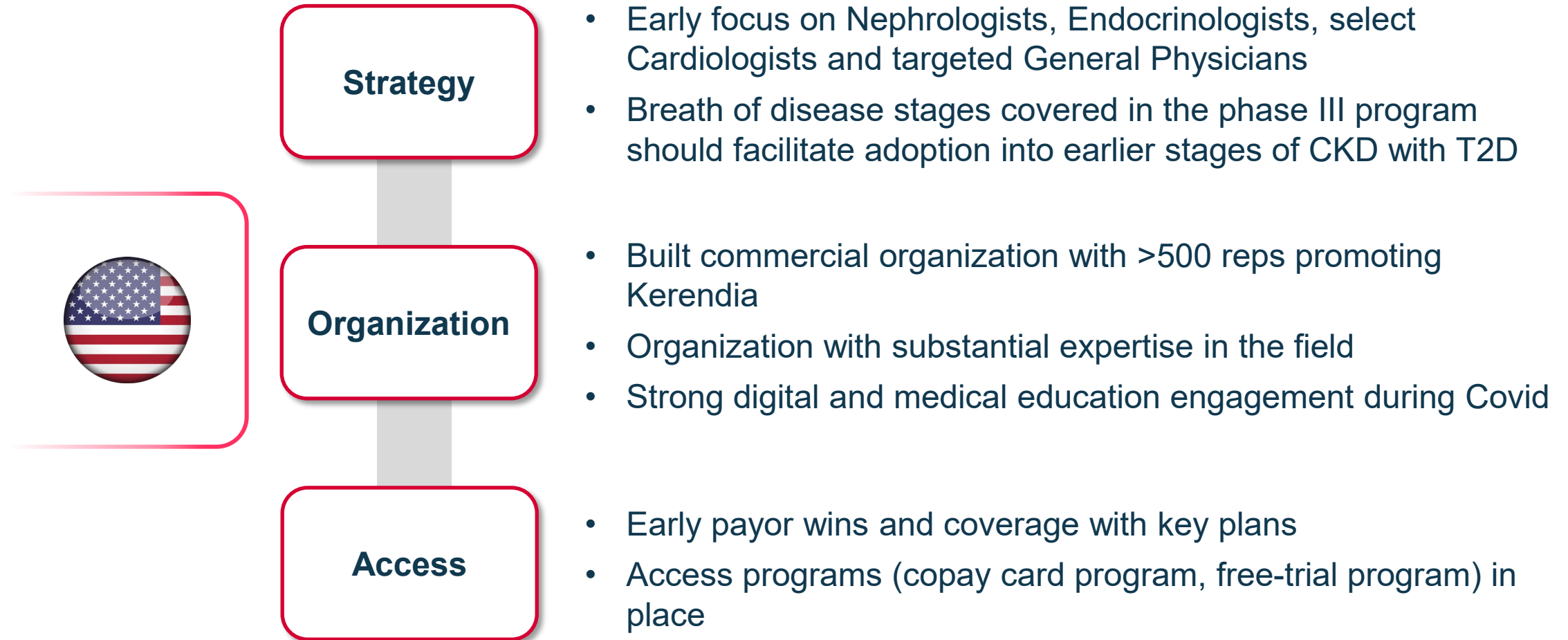


Filed 2/2021

**Global
launch**



Significant investment to tap into a targeted portion of the US primary care market with Kerendia





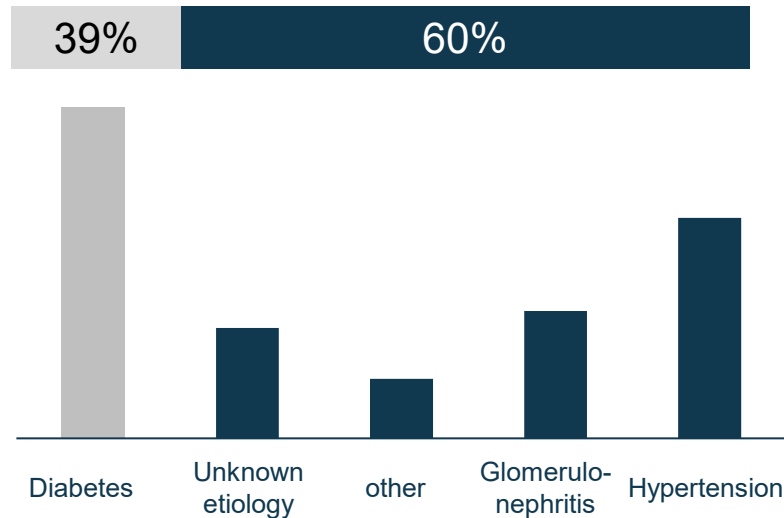
Life-cycle management for Finerenone into non-diabetic CKD and into heart failure

Non-diabetic CKD



CKD attributable to causes such as hypertension or chronic glomerulonephritis

Reported cases of ESRD (US)



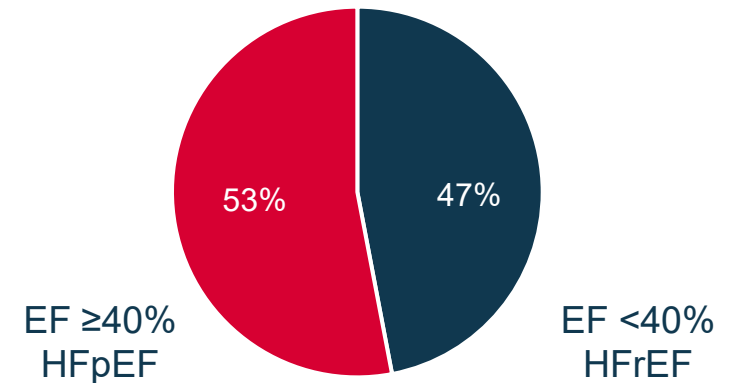
<https://www.cdc.gov/kidneydisease/publications-resources/annual-report/ckd-related-health-problems.html>
Owan T.E. et al, N Engl J Med 2006

Heart Failure



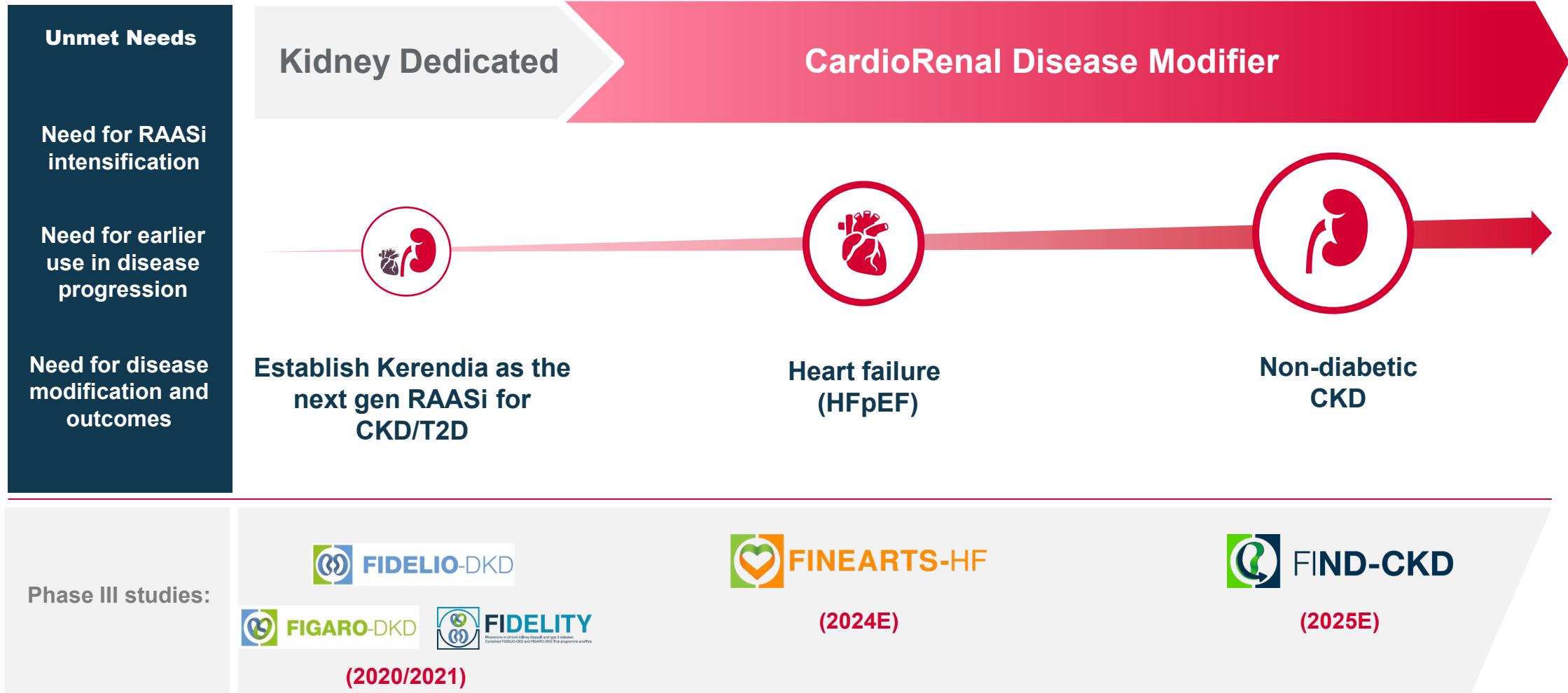
Targeting HF with a left ventricular ejection fraction of $\geq 40\%$ (HFpEF).

HF patient population by left ventricular ejection fraction





Kerendia sets the stage for a long-term cardio-renal vision and targets to deliver blockbuster potential



Dates indicate primary trial completion according to clinicaltrials.gov

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Abbreviations

ACEi	Angiotensin converting enzyme inhibitor	PSP	Peak sales potential
AE	Adverse event	RAAS	Renin-angiotensin-aldosterone system
ARB	Angiotensin receptor blocker	RASi	Renin-angiotensin-system inhibition/inhibitor
BD&L	Business development and licensing	SGLT-2i	Sodium-glucose-cotransporter 2 inhibitor
CI	Confidence interval	SOC	Standard of care
CKD	Chronic kidney disease	T2D	Type-2-diabetes
CV	Cardiovascular	UACR	Urine albumin-to-creatinine ratio
DKD	Diabetic kidney disease	WH	Women´s health
EF	Ejection fraction		
eGFR	Estimated glomerular filtration rate		
ESRD	End-stage renal disease		
HCP	Healthcare provider		
HF	Heart failure		
HFpEF	Heart failure with preserved ejection fraction		
HFrEF	Heart failure with reduced ejection fraction		
HK	Hyperkalemia		
HR	Hazard ratio		
LoE	Loss of exclusivity		
MOA	Mode of action		
MR	Mineralocorticoid receptor		
MRA	Mineralocorticoid receptor antagonist		
NNT	Number needed to treat		