KERENDIA: A proven approach for reducing cardiorenal risk in patients with CKD associated with T2D

KERENDIA was studied in adults with CKD associated with T2D in 2 phase 3, randomized, double-blind, placebo-controlled, multicenter trials as part of a comprehensive clinical program[1]

As published in the *New England Journal of Medicine*[2]

CV outcomes trial

FIGARO-DKD

https://www.nejm.org/doi/full/10.1056/NEJMoa2110956

As published in the *New England Journal of Medicine*[3]

Renal outcomes trial

FIDELIO-DKD

https://www.nejm.org/doi/full/10.1056/NEJMoa2025845

The prespecified exploratory pooled analysis of the CV outcomes trial and Renal outcomes trial

As published in the *European Heart Journal*[1,4]

FIDELITY

ACEi=angiotensin-converting enzyme inhibitor; ARB=angiotensin receptor blocker; CKD=chronic kidney disease; CV=cardiovascular; T2D=type 2 diabetes.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8830527/

INDICATION:

- KERENDIA is 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)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

- Concomitant use with strong CYP3A4 inhibitors
- Patients with adrenal insufficiency

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In adult patients with CKD associated with T2D[1]

KERENDIA was studied across a broad range of CKD severity[1]

CV outcomes trial[4]
FIGARO-DKD (N=7352)
Majority earlier-stage (1-2) CKD patients (defined as eGFR ≥60 mL/min/1.73 m² with albuminuria)[2,5]

Primary CV composite endpoint:
- CV death
- Non-fatal MI
- Non-fatal stroke
- HF hospitalization

Secondary renal composite endpoint:
- Kidney failure
- Sustained decline of ≥40% in eGFR
- Renal death

Renal outcomes trial[4]
FIDELIO-DKD (N=5674)
Majority later-stage (3-4) CKD patients (defined as eGFR <60 mL/min/1.73 m² with albuminuria)[3,5]

Primary renal composite endpoint:
- Kidney failure
- Sustained decline of ≥40% in eGFR
- Renal death

Secondary CV composite endpoint:
- CV death
- Non-fatal MI
- Non-fatal stroke
- HF hospitalization

FIDELITY*
Prespecified exploratory pooled analysis of safety and efficacy data from the FIGARO-DKD and FIDELIO-DKD trials[1] (N=13,026)

	FIGARO-DKD	FIDELIO-DKD
Select inclusion criteria for adult patients with CKD associated with T2D[4]		
eGFR/albuminuria	eGFR 25 to 90 mL/min/1.73 m² with a UACR of 30 to <300 mg/g **OR** eGFR ≥60 mL/min/1.73 m² with a UACR ≥300 mg/g	eGFR 25 to <60 mL/min/1.73 m² with with a UACR of 30 to <300 mg/g and diabetic retinopathy **OR** eGFR 25 to <75 mL/min/1.73 m² with a UACR ≥300 mg/g
Medications	Treated with standard-of-care background therapy, including maximum tolerated dose of either an ACEi or an ARB	
Serum potassium	Serum potassium ≤4.8 mEq/L at screening	
Select exclusion criteria for adult patients with CKD associated with T2D[1]		
Other conditions	Symptomatic chronic HF with reduced ejection fraction (New York Heart Association class II-IV)	
	Known significant non-diabetic kidney disease	

*Statistical analyses were prespecified exploratory evaluations rather than hypothesis confirming; therefore, no adjustment for multiplicity was performed.
eGFR=estimated glomerular filtration rate; HF=heart failure; MI=myocardial infarction.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS:

- ***Hyperkalemia:*** KERENDIA can cause hyperkalemia. The risk for developing hyperkalemia increases with decreasing kidney function and is greater in patients with higher baseline potassium levels or other risk factors for hyperkalemia. Measure serum potassium and eGFR in all patients before initiation of treatment with KERENDIA and dose accordingly. Do not initiate KERENDIA if serum potassium is >5.0 mEq/L

  Measure serum potassium periodically during treatment with KERENDIA and adjust dose accordingly. More frequent monitoring may be necessary for patients at risk for hyperkalemia, including those on concomitant medications that impair potassium excretion or increase serum potassium

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KERENDIA clinical trial program

Largest CKD associated with T2D clinical trial program, studied across >13,000 patients[1]

the *New England Journal of Medicine*

Cardiovascular Events with Finerenone in Kidney Disease and Type 2 Diabetes

Bertram Pitt, MD, Gerasimos Filippatos, MD, Rajiv Agarwal, MD, Stefan D. Anker, MD, PhD, George L. Bakris, MD, Peter Rossing, MD, Amer Joseph, MB, BS, Peter Kolkhof, PhD, Christina Nowack, MD, Patrick Schloemer, PhD, and Luis M. Ruilope, MD, for the FIGARO-DKD Investigators

Review the full FIGARO-DKD trial

https://www.nejm.org/doi/full/10.1056/NEJMoa2110956

the *New England Journal of Medicine*

Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes

George L. Bakris, MD, Rajiv Agarwal, MD, Stefan D. Anker, MD, PhD, Bertram Pitt, MD, Luis M. Ruilope, MD, Peter Rossing, MD, Peter Kolkhof, PhD, Christina Nowack, MD, Patrick Schloemer, PhD, Amer Joseph, MB, BS, and Gerasimos Filippatos, MD, for the FIDELIO-DKD Investigators

Review the full FIDELIO-DKD trial

https://www.nejm.org/doi/full/10.1056/NEJMoa2025845

These independent, peer-reviewed articles may contain data, conclusions, and recommendations that do not conform to the FDA-approved labeling for the product discussed therein. KERENDIA *should be used only as specified in the full Prescribing Information.*

the *European Heart Journal*

Cardiovascular and kidney outcomes with finerenone in patients with type 2 diabetes and chronic kidney disease: the FIDELITY pooled analysis

Rajiv Agarwal, Gerasimos Filippatos, Bertram Pitt, Stefan D Anker, Peter Rossing, Amer Joseph, Peter Kolkhof, Christina Nowack, Martin Gebel, Luis M Ruilope, George L Bakris, and FIDELIO-DKD and FIGARO-DKD investigators

See the full FIDELITY analysis

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8830527/

IMPORTANT SAFETY INFORMATION (cont'd)

MOST COMMON ADVERSE REACTIONS:

- From the pooled data of 2 placebo-controlled studies, the adverse reactions reported in ≥1% of patients on KERENDIA and more frequently than placebo were hyperkalemia (14% vs 6.9%), hypotension (4.6% vs 3.9%), and hyponatremia (1.3% vs 0.7%)

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For your adult patients with CKD associated with T2D

KERENDIA: At the heart of cardiorenal treatment[4]

LARGEST
cardiorenal outcomes program of >13,000 patients with CKD associated with T2D[1]

ESTABLISHED
efficacy and safety across a broad range of CKD severity[4]

PROVEN
dual cardiorenal risk reduction[4]

INDICATION:

- KERENDIA is 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)

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS:

- ***Strong CYP3A4 Inhibitors:*** Concomitant use of KERENDIA with strong CYP3A4 inhibitors is contraindicated. Avoid concomitant intake of grapefruit or grapefruit juice
- ***Moderate and Weak CYP3A4 Inhibitors:*** Monitor serum potassium during drug initiation or dosage adjustment of either KERENDIA or the moderate or weak CY P3A4 inhibitor and adjust KERENDIA dosage as appropriate
- ***Strong and Moderate CYP3A4 Inducers:*** Avoid concomitant use of KERENDIA with strong or moderate CYP3A4 inducers

USE IN SPECIFIC POPULATIONS:

- ***Lactation:*** Avoid breastfeeding during treatment with KERENDIA and for 1 day after treatment
- ***Hepatic Impairment***: Avoid use of KERENDIA in patients with severe hepatic impairment (Child Pugh C) and consider additional serum potassium monitoring with moderate hepatic impairment (Child Pugh B)

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References: 1. Agarwal R, et al. *Eur Heart J.* 2022;43(6):474-484. doi:10.1093/eurheartj/ehab777. **2.** Pitt B, et al. *N Engl J Med.* 2021;385(24):2252-2263. doi:10.1056/NEJMoa2110956. **3.** Bakris GL, et al; FIDELIO-DKD Investigators. *N Engl J Med.* 2020;383(23):2219-2229. doi:10.1056/NEJMoa2025845. **4.** KERENDIA (finerenone) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; September 2022. **5.** Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. *Kidney Intl Suppl.* 2013;3(1):1-150. doi:10.1038/kisup.2012.73.

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