

FIDELIO-DKD and FIGARO-DKD Clinical Trial Programs

The program comprises two studies evaluating the effect of investigational finerenone versus placebo on top of standard of care[†] on both kidney and cardiovascular (CV) outcomes.^{1,2}

Inclusion Criteria:

- Men or women ≥18 years of age
- Subjects with Type 2 diabetes mellitus as defined by the American Diabetes Association
- Diagnosis of diabetic kidney disease (DKD) with persistent high albuminuria or persistent very high albuminuria at the Run-in and Screening visits:
 - Pretreated with either angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) at maximal tolerated labeled dose without adjustments
 - Serum potassium ≤4.8 mmol/L

>13,000
Randomized patients

FIDELIO-DKD

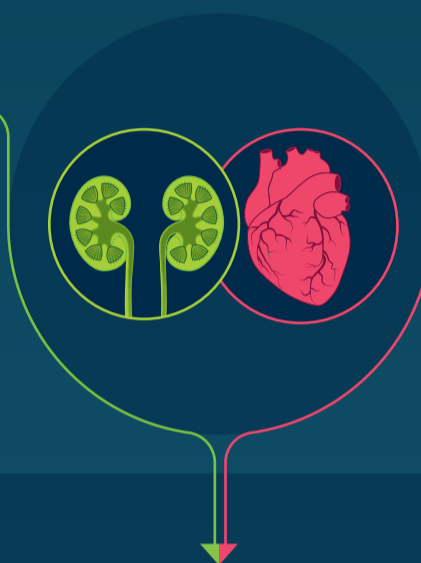
Finerenone in reducing **ki**DnEy faiLure and **d**isease prOgression in **DKD***

Patient recruitment has concluded and the study concluded April 2020.¹

FIGARO-DKD

Finerenone in reducin**G** **c**ardiovascular **m**ortality and **m**orbidity in **DKD***

Patient recruitment concluded in 2018 and the study is due to complete mid-2021.²



FIDELIO-DKD & FIGARO-DKD study design^{1,2}

Finerenone is being investigated in 48 countries

10-20 mg once daily on top of standard of care compared with placebo on top of standard of care[†], in patients with CKD and T2D



Completed **April 2020** Event-driven studies Due to complete **mid-2021**

FIDELIO-DKD

Primary endpoint:



Time to the first occurrence of the composite endpoint of onset of kidney failure indicated by either a sustained decrease of estimated glomerular filtration rate (eGFR) ≥ 40% from baseline over at least 4 weeks or renal death. [Time Frame: Time to total Follow up (Up to 48 months)]

Key secondary endpoints:



Time to first occurrence of the composite endpoint: cardiovascular death or non-fatal cardiovascular events (myocardial infarction, stroke, hospitalization for heart failure) [Time Frame: Time to total Follow up (Up to 48 months)]

Time to all-cause mortality [Time Frame: Time to total Follow up (Up to 48 months)]

Time to all-cause hospitalizations [Time Frame: Time to total Follow up (Up to 48 months)]

Time to first occurrence of the following composite endpoint: onset of kidney failure, a sustained decrease in estimated glomerular filtration rate (eGFR) of ≥ 57% from baseline over at least 4 weeks or renal death. [Time Frame: Time to total Follow up (Up to 48 months)]

Change in urinary albumin-to-creatinine ratio (UACR) from baseline to month 4 [Time Frame: Baseline to Month 4]

FIGARO-DKD

Primary endpoint:



Time to the first occurrence of the composite endpoint of cardiovascular death and non-fatal cardiovascular events (myocardial infarction, stroke, or hospitalization for heart failure) [Time Frame: Time to total Follow up (Up to 53 months)]

Key secondary endpoints:



Time to first occurrence of the following composite endpoints: onset of kidney failure, a sustained decrease in estimated glomerular filtration rate (eGFR) of ≥40% from baseline over at least 4 weeks and renal death [Time Frame: Time to total Follow up (Up to 53 months)]

Time to all-cause mortality [Time Frame: Time to total Follow up (Up to 53 months)]

Time to all-cause hospitalization [Time Frame: Time to total Follow up (Up to 53 months)]

Change in urinary albumin-to-creatinine ratio (UCAR) from baseline to month 4 [Time Frame: Baseline to Month 4]

Time to first occurrence of the following composite endpoint: onset of kidney failure, a sustained decrease in estimated glomerular filtration rate (eGFR) of ≥ 57% from baseline over at least 4 weeks or renal death. [Time Frame: Time to total Follow Up (Up to 53 months)]

*Diabetic Kidney Disease (DKD) and Chronic Kidney Disease in Type 2 Diabetes are used synonymously

[†]Standard of care is treatment according to national guidelines including either an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker.

References:

1. ClinicalTrials.gov. Efficacy and Safety of Finerenone in Subjects with Type 2 Diabetes Mellitus and Diabetic Kidney Disease (FIDELIO-DKD). 2015. Available at: <https://clinicaltrials.gov/ct2/show/NCT02540993>. Last accessed: September 2020. 2. ClinicalTrials.gov. Efficacy and Safety of Finerenone in Subjects with Type 2 Diabetes Mellitus and the Clinical Diagnosis of Diabetic Kidney Disease (FIGARO-DKD). 2015. Available at: <https://clinicaltrials.gov/ct2/show/NCT02545049>. Last accessed: September 2020.